

Matching Treatment to Patient Needs in Opioid Substitution Therapy *Treatment Improvement Protocol (TIP) Series* 20

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The opinions expressed herein are the views of the consensus panel members and do not reflect the official position of CSAT or any other part of the U. S. Department of Health and Human Services (DHHS). No official support or endorsement of CSAT or DHHS for these opinions or for particular instruments or software that may be described in this document is intended or should be inferred. The guidelines proffered in this document should not be considered as substitutes for individualized patient care and treatment decisions.

What Is a TIP?

CSAT Treatment Improvement Protocols (TIPs) are prepared by the Quality Assurance and Evaluation Branch to facilitate the transfer of state-of-the-art protocols and guidelines for the treatment of alcohol and other drug (AOD) abuse from acknowledged clinical, research, and administrative experts to the Nation's AOD abuse treatment resources.

The dissemination of a TIP is the last step in a process that begins with the recommendation of an AOD abuse problem area for consideration by a panel of experts. These include clinicians, researchers, and program managers, as well as professionals in such related fields as social services or criminal justice.

Once a topic is selected, CSAT creates a Federal resource panel, with members from pertinent Federal agencies and national organizations, to review the state of the art in treatment and program management in the area selected. Recommendations from this Federal panel are then communicated to the members of a second group, which consists of non-Federal experts who are intimately familiar with the topic. This group, known as a non-Federal consensus panel, meets in Washington for 5 days, makes recommendations, defines protocols, and arrives at agreement on protocols. Its members represent AOD abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A Chair (or co-Chairs) for the panel is charged with the responsibility for ensuring that the resulting protocol reflects true group consensus.

The next step is a review of the proposed guidelines and protocol by a third group whose members serve as expert field reviewers. Once their recommendations and responses have been reviewed, the Chair approves the document for publication. The result is a TIP reflecting the actual state of the art of AOD abuse treatment in public and private programs recognized for their provision of high quality and innovative treatment.

This TIP, *Matching Treatment to Patient Needs in Opioid Substitution Therapy*, offers guidelines to providers who are working to deliver the best treatment possible to opiate-addicted persons. Patients in this population often need a broad range of services in addition to opioid substitution therapy, and research has shown that providing these services as part of the therapy program greatly increases retention in treatment and improves outcomes. The TIP provides a model for matching patients to services that takes into account the changing needs of patients at different

phases of treatment. The TIP outlines a comprehensive assessment process for identifying patient needs and describes core treatment elements for addressing those needs. Because evaluation and self-monitoring are important ways to ensure that programs stay responsive to patient needs, the TIP presents step-by-step guidelines to assist programs in designing and implementing evaluation studies.

The TIP includes a chapter on costs of opioid substitution therapy that reviews several approaches to determining the costs and benefits of matching patients to needed services.

This TIP represents another step by CSAT toward its goal of bringing national leadership to bear in the effort to improve AOD abuse treatment.

Other TIPs may be ordered by contacting the National Clearinghouse for Alcohol and Drug Information (NCADI), (800) 729-6686 or (301) 468-2600; TDD (for hearing impaired), (800) 487-4889.

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Foreword

The Treatment Improvement Protocol (TIP) series fulfills CSAT's mission to improve alcohol and other drug (AOD) abuse and dependency treatment by providing best practices guidance to clinicians, program administrators, and payers. This guidance, in the form of a protocol, results from a careful consideration of all relevant clinical and health services research findings, demonstration experience, and implementation requirements. A panel of non-Federal clinical researchers, clinicians, program administrators, and patient advocates employs a consensus process to produce the product. This panel's work is reviewed and critiqued by field reviewers as it evolves.

The talent, dedication, and hard work that TIPs panelists and reviewers bring to this highly participatory process have bridged the gap between the promise of research and the needs of practicing clinicians and administrators. We are grateful to all who have joined with us to contribute to advance our substance abuse treatment field.

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Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series

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Chapter 1 -- Patient Matching: Historical Perspective and Overview

The purpose of this Treatment Improvement Protocol (TIP) is to develop guidelines to assess the needs of patients in opioid substitution therapy and to match patients, based on their needs, to a variety of services, including medical, psychiatric, social, and other support services. Several studies show that patients who receive the services they need are more likely than others to stay in treatment and to have positive outcomes. The concept of matching patients to services according to their needs is widely accepted in other medical treatment settings but until recently was not used in the field of opioid substitution therapy. This TIP details the current knowledge about patient matching in opioid substitution therapy; its goal is to help programs more fully develop the important aspects of treatment that derive from matching strategies.

Another TIP in this series, *State Methadone Treatment Guidelines*, presents a structure for States to follow to comply with Federal regulations when providing methadone treatment (the most common form of opioid substitution therapy). The methadone document describes the best treatment practices in separate chapters on admissions procedures, dose determination, use of urinalysis as a clinical tool, take-home medication, and patient retention. The methadone guidelines discuss the provision of methadone treatment to pregnant women, multiple substance abusers, and persons with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and other infectious diseases. The TIP on methadone also discusses matching strategies.

The current TIP focuses on ways to develop matching strategies on a comprehensive, programmatic level. This TIP and the previous one provide useful information about the best practices for providing opioid substitution therapy and about how to improve patients' chances for recovery by matching services to patient needs.

This document on patient matching continues the efforts of the Center for Substance Abuse Treatment (CSAT) to ensure that opioid substitution therapy programs throughout the United States provide high-quality, cost-effective services. Two other TIPs *LAAM in the Treatment of Opiate Addiction and Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients* provide information on delivering the highest quality and most cost-effective treatments to the broadest range of persons with opiate dependence.

In addition, this TIP on patient matching describes a further evolution of opioid substitution therapy as an effective treatment. The epidemics of AIDS and tuberculosis (TB) and the advent of managed care have a strong influence on opioid substitution therapy programs. These

epidemics make it more important than ever that programs find ways to address the wide range of patient needs, retain patients in treatment, and use resources efficiently. Patient matching is a critical strategy in attaining these goals.

In recent years, phased treatment models have been developed to help planners and providers better conceptualize opioid substitution therapy to improve service delivery and resource allocation. This document presents a six-phase treatment model, which includes an initial evaluation and an ongoing assessment of progress; it describes patient treatment needs during each phase and the types of services that can best meet these needs. Since effective patient matching depends on careful ongoing assessment, this TIP outlines the assessment process and describes clinical indicators for transition to other treatment phases. It also reviews treatment elements, including a core group of treatment and support services and a variety of counseling and therapeutic services that will enable opioid substitution therapy programs to meet patient needs via matching strategies.

Also addressed are the issues of program self-evaluation and cost-benefit analysis to help programs stay responsive to the realities of managed care and to provide input into managed-care policies and decisions.

Managed Care and Opioid Substitution Therapy

Managed care is an evolving process that was first developed in the private sector, mainly for individuals who are regularly employed. It was only recently applied to the public sector and to opioid substitution therapy programs. Many States are moving toward the use of a managed care model to provide healthcare services to Medicaid patients. The public sector, especially substitution programs, has large numbers of chronically ill and disadvantaged persons with multiple problems. Persons with multiple and chronic problems present a special dilemma for managed care programs, which traditionally focus on achieving cost savings by reducing or denying services. This strategy may be cost effective when applied to relatively healthy persons with illnesses that are usually time limited; it may be counterproductive if applied unwisely to opioid substitution therapy, which is a long-term process.

On the other hand, the managed care approach has considerable potential to facilitate treatment matching within opioid substitution therapy programs, provided that the managed care entity is held responsible for treating the medical, psychiatric, family, social, and other problems of patients in the program's care. When managed care organizations attempt to help the patient to obtain the most cost-effective medical, psychiatric, and other services for opioid substitution therapy, they do so within the opioid substitution programs. Emergency psychiatric and medical hospitalizations can be reduced when appropriate outpatient treatment and preventive services are provided to persons who are high users of inpatient treatment.

Thus, managed care, rather than being regarded as a nemesis for opioid substitution therapy, can be seen as having the potential to support this treatment, especially in regard to developing effective matching strategies. The reasons are financial. Very high costs result when patients are hospitalized. Most opioid-dependent patients are potential frequent users of hospital beds -- for detoxification or for psychiatric, medical, surgical, or other conditions that may or may not be

related to their substance use disorder. It is most cost effective to prevent hospitalization (including emergency room use) by ensuring that opioid substitution therapy programs have the professional resources necessary to develop effective psychiatric, medical, and other matching strategies.

Many of the services described in this TIP have not been routinely available to most substitution therapy programs. However, they may become more available when managed care organizations fully realize the cost savings that can be achieved by using matching strategies and outpatient professional services to prevent hospitalization and other more expensive treatments. If this view is held, managed care could help opioid substitution therapy programs to become the backbone of an effective outpatient, medical, and psychiatric treatment delivery system, which functions to reduce overall health costs for a group of patients who are high users of expensive inpatient services.

Although the managed care approach may be cost effective when applied to relatively healthy persons with time-limited illnesses, it has a great potential to be extremely counterproductive if applied to long-term therapy.

Many States currently lack a model to assess the appropriateness of treatment levels and patient matching in opioid substitution therapy programs. Models could be based on those being considered for treatment of other chronic diseases, such as HIV infection, that recognize the chronic nature of the condition and the need for extended therapy. It is very important that opioid substitution therapy programs work with managed care companies to establish assessment and treatment guidelines that are both cost effective and that match the needs of the patients.

Patient Matching

Patient matching is the process of individualizing treatment resources to patient needs and preferences. It requires an assessment of the extent, nature, and duration of the individual's alcohol and other drug (AOD) use and treatment history, as well as an assessment of medical, psychiatric, and psychosocial needs and functional status. The patient's gender, culture, ethnicity, sexual orientation, and language are of key importance. Matching is a participatory activity that involves both the clinician and the patient. Also important is the patient's motivation as well as the level of support available to the patient to achieve and maintain a life-style free of AOD abuse.

Most patients who require opioid substitution therapy have long-term, chronic addiction ailments that cause serious problems in many life areas. Patient matching should be undertaken with the understanding that many persons who are addicted to opioids have multiple needs. Because of the complexity of patients' needs and the scope of services required, matching is best accomplished through a three-step process that involves 1) assessing, 2) selecting the most suitable treatment modality and site, and 3) identifying the most appropriate ancillary services.

An individualized treatment plan with well-defined short- and long-term goals is the product of the patient-matching process. This plan is reevaluated at regular intervals to determine if it should be modified in respect to new issues that may arise as earlier identified problems are resolved.

Advantages of Patient Matching

Data from matching studies have become available only within the last 10 to 15 years, and thus the subject of this TIP is relatively new. In addition, the available data address relatively few of the many areas that could be investigated in this complex subject. However, the available data indicate that matching increases the likelihood of positive treatment outcomes. Provision of individualized, comprehensive services were shown to increase rates of retention in treatment ([Condelli, 1993](#); [Joe et al., 1991](#)); the longer a patient is in treatment, the better the chances for recovery.

Matching also improves resource allocation by ensuring that patients receive the appropriate level and type of services. It ensures appropriate use of the specific training and experience of all members of the multidisciplinary clinical team, thereby increasing the quality of care as well as team members' job satisfaction. The short-term cost of providing individualized, professionalized services may be higher than that of providing more limited care. However, the ultimate cost to the healthcare system and to society, as measured in terms of increased productivity and reduction in criminal activity, is likely to be greatly reduced.

The Need for Patient Matching Guidelines

The idea of patient matching, while not new, has become more attractive in the wake of pressures to contain the overall cost of healthcare, particularly if matching in an outpatient setting can reduce the need for hospitalization. Nonetheless, the concept of matching is as methodologically elusive to researchers as it is attractive to clinicians ([McLellan and Alterman, 1991](#)), and many of the basic concepts of patient matching have not yet been clearly defined or fully accepted. As additional data becomes available, these problems may be resolved.

The services that are described in this TIP may become more available when managed care organizations fully realize the cost savings that can be achieved by using matching strategies and outpatient professional services.

One example of the early development of the concept of patient matching within the substance abuse treatment field is that, despite the existence of detailed Federal and State regulations, methadone treatment services and outcomes vary dramatically from program to program ([Ball and Ross, 1991](#); [General Accounting Office, 1990](#)). Some programs are still basing patient management decisions on outdated clinical paradigms that are not consistent with current research findings. For example, many programs administer low dosages of methadone (i.e., 25-

40 mg as the average) in the belief that lower is better, despite the abundant research supporting the efficacy of higher dosages (60 mg or more), with dosage levels individualized for each patient. Further, some programs encourage time-limited treatment rather than long-term substitution therapy. In these cases, clinical practice does not reflect research findings that demonstrate the efficacy of higher doses and long-term, very extended, or even indefinite treatment.

In other cases, State regulations prohibit the use of methadone in settings and modalities that are an important part of treatment matching and the continuum of care. For example, consider the case of a homeless patient who might do well on substitution therapy if he or she had a stable living arrangement; however, the housing or shelter that could provide such an arrangement does not admit persons on methadone. Another example is the case of a methadone-maintained patient who needs brief hospitalization for medically supervised withdrawal (detoxification) from another substance, but the detoxification program does not allow the patient to be maintained on methadone during the process.

This TIP describes the problems and points out rules that need attention and revision. As a result, it is hoped that some regulations will be modified to become more consistent with an integrated, comprehensive system of treatment that includes patient matching within a continuum of care.

The lack of resources and staff to provide an appropriate range of services is an impediment to developing matching strategies within the current AOD, health, psychiatric, and social service systems. There is a tendency in some programs to wall off substance abuse treatment from other services, as if to say, "We are responsible only for the substance use disorder and nothing else." This type of organizational structure is a significant obstacle to the use of effective matching strategies and often inconveniences the patient to the point that he or she does not comply with important treatment recommendations. In addition, it runs counter to AOD provider's growing awareness of the need to develop increasingly effective systems of primary care that treat the whole person.

Regulations in some States prohibit the use of methadone in settings and modalities that are an important part of treatment matching and the continuum of care.

It is not necessary for each program to offer the full spectrum of needed resources and services to successfully apply patient-matching techniques. Through staff training and the use of carefully developed referral networks supported by appropriate guidelines, staff can identify the need for additional services and work with patients to offer them access to services that a single program is unable to provide. Psychiatric, medical, and social work services are the most commonly needed and used. Programs should place the highest priority on obtaining resources or developing relationships with providers that can provide these services in a convenient and cost-effective manner.

The remainder of this chapter provides a historical review of the development of opioid substitution therapy and ongoing treatment issues. HIV/AIDS and the concept of harm reduction are discussed, and additional comments about the impact of managed care on the delivery of substitution therapy are reviewed.

Historical Perspective

When new treatments are developed, matching patients to these treatments can be done relatively quickly. Clinicians in most medical settings readily accept the concept of matching. There are numerous examples of this phenomenon. For instance, clinicians began using a combination of drugs to treat HIV infection when it was found that the HIV virus was able to quickly develop resistance to AZT when it was used alone ([Cheesman et al., 1994](#)).

However, in the case of opioid substitution therapy, the progression from the development of a treatment for a very serious disorder to further treatment refinements, including the use of matching strategies, has been delayed. For example, many single State agencies have been slow to approve use of the opioid substitute levo-alpha-acetyl-methadol (LAAM), even though its use reduces the risk of diversion. In addition, although methadone has now been used for almost 30 years, patient-treatment matching strategies have only just begun to be formally addressed in opioid substitution therapy programs.

Reasons for this halting progression may be found in the historical development of substitution therapy and in the ambivalence that has always surrounded its use. Treatment of opioid dependence with substitution therapy has been tried in isolated cases by individual practitioners and applied on a larger scale as part of organized treatment programs for at least 100 years. Until the advent of methadone maintenance in the 1960s, there was little or no scientific evidence that opioid substitution therapy was generally helpful. Perhaps because of this lack of evidence, reports of improper use, and diversion of legally prescribed opioids, substitution therapy fell into public disrepute during the 1920s.

An administrative structure to control prescription and consumption of addictive substances was put into place by the Harrison Act of 1914, which required dispensers of opioids and cocaine to register annually, to pay a fee, and to use special forms provided by the Internal Revenue Service. This move toward more controls on addictive substances was consistent with the temperance movement and the enactment of Prohibition in 1919. These structures to introduce controls over prescribing, though seemingly modest in scope, were interpreted by law enforcement agencies in increasingly restrictive ways beginning in the 1920s. As a result, the few physicians who continued to prescribe opioids to addicted persons were forced to discontinue this practice; to do so, even in the absence of diversion or overt criminal behavior, became defined as an illegal act that could result in suspension of a physician's medical license or even a prison sentence.

This movement toward strict limits on prescribing was greatly strengthened under the leadership of Harry Anslinger, who was commissioner of the Federal Bureau of Narcotics (FBN) from 1930 to 1964. (The FBN became the Drug Enforcement Administration [DEA] in 1973.) Treatment became totally abstinence oriented, and two Federal hospitals with long-term residential settings

were established during the 1930s to treat opiate-addicted individuals. One hospital was at Lexington, Kentucky, and the other at Fort Worth, Texas. Each hospital accepted voluntary patients as well as prisoners who had been convicted of Federal crimes that were often related to opiate dependence. Much of the early research on opioid dependence was conducted in these settings, especially the Lexington facility. These treatment facilities were very small and required patients to remain for long periods in residential therapy. In addition, they were expensive, and although patients improved, relapse rates were high after discharge from the residential setting.

Treatment of opiate dependence with substitution therapy has been tried in isolated cases by individual practitioners and applied on a larger scale as part of organized treatment programs for at least 100 years. With the advent of methadone maintenance studies in the 1960s, scientific evidence established that opioid substitution therapy is often effective.

In the early 1960s, Drs. Marie Nyswander and Vincent Dole became interested in opioid addiction and relapse. They were aware of the problems that had been associated with previous attempts at substitution therapy but did not give up on the idea. They began to examine methadone as a possible solution. This drug had been developed during World War II by Germany when its opiate supplies were interrupted by the war. Methadone has all the pharmacological effects of other opioids; however, it also has two properties which make it potentially useful for substitution therapy: 1) It is well absorbed when given orally, and 2) it suppresses opioid withdrawal symptoms for 24 to 36 hours.

Thus, a single oral dose of methadone can prevent opiate withdrawal symptoms for a day, while also avoiding the complications associated with parenteral use. Using high doses of methadone for substitution therapy was found to produce significant cross-tolerance to illicit opiate, thus diminishing the high produced by heroin, which further contributed to methadone's efficacy. In addition, methadone provides much more control over diversion or improper use, since a single daily dose can be administered under direct observation.

Dole and Nyswander began a series of experiments in which they selected persons with a long history of opioid dependence who were free of serious medical or psychiatric problems and who were willing to participate in a study of methadone substitution therapy (Dole and Nyswander, [1966](#); [1967](#)). Careful followup showed a significant change in the behavior that had been typical of these patients. Illicit heroin use and criminal behavior were markedly reduced, patients' sense of well-being and self-respect were significantly improved, employment increased, and family problems were improved. In addition, medical evaluations demonstrated no significant adverse effects as a consequence of long-term maintenance (Kreek, [1973](#); [1978](#); [1983](#)). On the basis of these early and very positive results, methadone was approved in the early 1970s by the Food and Drug Administration (FDA) as a substitution therapy for chronic opioid users who had demonstrated an inability to achieve sustained abstinence.

Change in Public Policy

Thus, after more than 50 years of public and legal opposition to substitution therapy, a new drug, methadone, had been studied, applied, and found effective. Within a period of several years, almost 100,000 opioid-addicted persons were being treated with methadone in the United States. Methadone maintenance became and remains the single treatment that is most acceptable to opiate-addicted individuals.

This marked change in policy occurred rapidly and was not without its opponents, especially among law enforcement agencies that had played a significant role in implementing the earlier restrictive policies. Some medical professionals, particularly those committed to long-term drug-free treatment, also opposed its use as did some lay persons and politicians who felt that it represented "giving in" to the problem or that it was another form of "slavery." These factors contributed to a lack of public and professional acceptance of opioid substitution therapy. In fact, attempts were made to arrest Dr. Dole, even after he reported the very positive results that could be achieved by methadone maintenance treatment.

Perhaps as a result of the legal and political ambivalence surrounding methadone maintenance, a large number of studies were done to confirm its efficacy ([Ball and Ross, 1991](#); [Dole and Joseph, 1978](#); [Dole and Nyswander, 1967](#); [Dole et al., 1966](#); [Gearing and Schweitzer, 1974](#); [Gerstein and Hartwood, 1990](#); [Hartel et al., 1988](#); [Kreek, 1983](#)). Though few found results as dramatic as those of the early studies of Dole and Nyswander, almost all studies confirmed the original findings: marked reductions in opioid use and crime and improvement in employment and overall social adjustment.

Federal Regulations and Public Policy

The Need for Regulations

Since methadone can be abused like any other opioid, regulations were developed by States, FDA, and DEA to limit and control its use. These regulations govern who can administer methadone maintenance, eligibility for treatment, evaluation procedures, dosages, take-home medications, frequency of patient visits, medical and psychiatric services, counseling, support services, and related details. The various regulations are complex, and State regulations are not always identical to FDA regulations. For example, Federal regulations do not specify a limit on time in treatment; however, some States and some programs set such limits. Similarly, some States limit dosages of methadone to 80 mg a day or less, a lower limit than is permitted by Federal regulations.

The FDA regulations were enacted in 1973 and revised in 1980 and 1989; they have been described in detail in a previous TIP *State Methadone Treatment Guidelines*. Copies of the most current FDA regulations are included in appendices to that document.

The FDA has responsibility for approving programs and ensuring compliance with FDA regulations; the DEA monitors the security of program facilities and compliance with regulations concerning the handling of controlled substances. Programs must also receive approval from the

State methadone authority, which monitors the same areas as the FDA and the DEA, and also serves as a source of technical assistance. In addition, methadone treatment programs must meet other requirements to be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Commission on Accreditation of Rehabilitation Facilities (CARF), if they choose to be certified by these agencies.

Influence of Regulations on Developing Matching Strategies

The emphasis on regulatory compliance that has dominated opioid substitution therapy programs since their inception has probably inhibited the development of patient-treatment matching strategies. Although it is probably necessary to have a clinically informed set of regulations that are reasonably enforced by qualified and well-trained persons (characteristics that have not always been the case [[Institute of Medicine, 1995](#)]), the regulatory emphasis has consumed so much of treatment providers' energy that it has in all likelihood diverted attention from more clinically focused activities and impaired the development of clinically focused approaches, such as matching strategies and treatment guidelines.

An emphasis on regulatory controls may have been necessary when opioid substitution therapy was first developed. However, the relevance of a regulatory emphasis at the present time is not so clear. For example, a recent report on methadone by the Institute of Medicine concluded that the emphasis on regulations has focused too much on protecting society from methadone and not enough on developing methadone programs to best help persons with opioid dependence and to protect society from the social disruption caused by heroin addiction ([Institute of Medicine, 1995](#)).

The potentially adverse effects of an overemphasis on regulatory control may be strongest in the area of patient-treatment matching. The original patients selected by Dole and Nyswander for substitution therapy were generally not polydrug abusers; they were free of serious medical or psychiatric problems. After methadone was approved for general use, a much more heterogeneous group of patients, in particular those with serious psychiatric and medical problems, was admitted to treatment. These patients did not progress as well as the original treatment group ([McLellan et al., 1983b](#)).

The number of multiplicatively impaired patients has been growing, especially since the AIDS epidemic. Patients with medical and psychiatric impairments are those who can best be served by treatment matching strategies; they usually do not progress unless these approaches are instituted. An emphasis on regulatory compliance or overly restrictive interpretation of existing regulations can impair the development of matching strategies and reduce the chances of good treatment outcomes for patients with multiple problems.

LAAM

LAAM is a long-acting opioid that can be used in place of methadone for opioid substitution therapy. It was approved by the FDA in July 1994, after two decades of study. Its effects are similar to those of methadone; that is, it creates a pharmacologic cross-tolerance to heroin and other opioids and therefore blocks the euphoric effects of those drugs while also controlling

craving. LAAM can suppress the signs and symptoms of opiate withdrawal for 48 to 72 hours, whereas methadone is effective for 24 to 36 hours.

A 1995 report on methadone by the Institute of Medicine concluded that the emphasis on regulations has focused too much on protecting society from methadone and not enough on developing methadone programs to best help persons with opioid dependence and to protect society from the social disruption caused by heroin addiction.

Use of LAAM allows patients to visit the clinic less frequently; instead of daily visits for methadone, LAAM can be administered every other day from the beginning of treatment. In addition, some patients report that they feel better on LAAM than on methadone, perhaps because of LAAM's longer duration of action. Some patients have reported a "smoother" effect, with fewer ups and downs.

LAAM is an alternative to methadone for opioid substitution therapy; it allows the patient and clinician another choice. Although LAAM has been approved by the FDA, it must also be approved by the individual State in which it is to be used. As of this writing, approximately 20 States have approved the use of LAAM, and it is being used in Portugal and several other European countries.

LAAM is discussed in detail in another TIP in this series, *LAAM in the Treatment of Opiate Addiction*.

Treatment Issues

Since opioid substitution therapy became widespread, some important treatment issues have come into focus. Several of these issues have a direct bearing on the ability of programs to effectively carry out patient-treatment matching. Two of the most important issues involve questions about the most effective methadone dose and the optimal level of psychosocial services to provide in substitution therapy programs. Other issues relate to the problems of polydrug abuse and to choosing the best approaches for treating dually diagnosed patients, dispensing take-home medications, and managing behavioral problems in the immediate vicinity of the methadone clinic facility.

Several studies have been done to explore the issues of dose, psychosocial services, and management of dually diagnosed patients. Studies of dose have shown conclusively that, although some patients do well on 30 to 50 mg per day, those on higher doses (60 mg per day or more) generally do better ([Ball and Ross, 1991](#)). One of the best designed of these studies was done by Ling and associates in the Veterans [Administration \(Ling et al., 1976\)](#). It showed that patients randomly assigned to receive 100 mg of methadone a day did significantly better than those receiving 50 mg a day. The more positive effects of higher doses are probably mainly a result of the significant levels of cross-tolerance that are obtained.

Other studies have addressed questions regarding the most appropriate levels of psychosocial services and the treatment of dually diagnosed patients. One of the most consistent findings of these studies is that there is no single predictor of success for patients in treatment. Some have problems only with substance abuse, while others have many problems, including psychiatric, legal, medical, family-social, and employment problems. Studies have usually found that the provision of more services is associated with better treatment outcomes. Studies that have more closely examined interactions between services and outcomes have found that patients are usually helped when services are targeted to specifically identified problems ([McLellan et al., 1993](#)). For example, studies have shown that professional psychotherapy given in addition to drug-focused paraprofessional counseling can improve outcomes of patients with recurrent and coexisting psychiatric symptoms ([Woody et al., 1991](#)).

Ambivalence about opioid substitution therapy continues in spite of the overwhelming scientific evidence of its effectiveness. Many people are uncomfortable maintaining patients on methadone for long periods, especially when maintenance may be indefinite. Some of the controversial issues focus on very real problems such as how best to treat methadone-maintained patients who abuse or are dependent on other drugs. Some programs want to withdraw from methadone those patients who have other AOD problems or serious medical or psychiatric problems. Use of cocaine, benzodiazepines, and alcohol has presented special difficulties, since administration of methadone does not directly address the use of these substances. Evidence is accumulating, however, that the psychosocial and behavioral aspects of methadone treatment programs are often helpful in suppressing nonopioid drug abuse ([Arndt, 1992](#); [McLellan et al. 1993](#)) however, psychosocial treatments alone leave much room for improvement.

Other issues sometimes focus on the goals of methadone treatment. Should methadone maintenance be a stepping stone to eventual abstinence, or is it an acceptable lifelong treatment? From the data, one could argue that it is an acceptable lifelong treatment for many patients but that some can achieve long-term and stable drug-free adjustment. Who are these patients, and how are they best identified? These questions need further research.

A current and important issue, and one on which little research data are available, is how to decide that methadone treatment either is appropriate for a patient or is not working. Studies indicate that overall drug use by most methadone patients is markedly reduced, even though total abstinence may not be achieved. Although the goal of most treatment providers is to maintain patients on methadone in the absence of illicit drug use, this goal is often not achieved. At what level of drug use does one conclude that methadone maintenance is not helping and another treatment should be tried, even to the point of terminating methadone treatment against the patient's wishes?

Ambivalence about opioid substitution therapy continues in spite of the overwhelming scientific evidence of its effectiveness. Many people are uncomfortable maintaining patients on methadone for long periods, especially when maintenance may be indefinite.

Decisions in this area have always been difficult, but they have become even more complex with the advent of HIV infection. As discussed later in this chapter, data are accumulating showing that opioid-addicted persons who are maintained on methadone have a substantially reduced chance of becoming infected with HIV, even though they might not completely stop illicit drug use ([Metzger et al., 1993](#)). At what point can it be said that enough harm reduction has occurred to justify continued methadone maintenance despite the fact that the patient's progress is not at the expected level? More data are needed to guide decisions in this area. Available data indicate that substantial risk reduction can occur without the achievement of total abstinence. However, patients who continue to use drugs may erode clinic morale as other patients come to the conclusion that compliance and abstinence are not expected.

In summary, although many important issues remain, the data strongly indicate that opioid substitution therapy can provide substantial benefits to persons with opioid dependence. This important point should not be obscured in our attempts to identify problems and improve upon methadone treatment, to find newer substitution therapies that may be more efficacious for some patients than methadone, such as LAAM, and to develop guidelines and strategies for treating addicted patients with opioid substitution therapy.

HIV/AIDS and Harm Reduction

As discussed earlier, there is growing evidence that involvement in opioid substitution therapy reduces the risk of HIV infection, even if illicit drug use is not completely eliminated. In addition, HIV-positive patients who are receiving substitution therapy are engaged in a treatment program in which they are seen frequently. Their engagement in treatment generally allows them better access to important medical services than they might otherwise have (provided the services are available). Engaging this patient population in continued care has significant public health implications. Not only can these patients receive treatment for HIV disease and its complications, but they also can receive counseling about the disease and about behavioral changes that will reduce the risk of HIV transmission.

A prime example of a public health benefit that can be achieved by effectively run opioid substitution therapy programs is screening for tuberculosis (TB), which has increased significantly in recent years, especially in association with HIV disease. The medical evaluations that occur at intake to substitution therapy programs provide an opportunity to identify patients who carry TB or have active TB. One of the difficulties of treating TB is that many persons fail to comply with medication regimens and must be carefully monitored. The frequent clinic visits that are part of opioid substitution therapy provide an opportunity for direct observation of antituberculosis pharmacotherapy.

A more recent harm reduction intervention is interim substitution therapy. This treatment involves daily administration of methadone without provision of regular counseling services. It is applicable only on a time-limited basis and only when there are waiting lists for methadone programs. The aim of interim therapy is to provide some reduction in opiate use while a patient is waiting for a place to open in a more fully staffed treatment program. Interim treatment has been found to decrease the use of heroin and other opioids; however, patients who participate in

programs in which more comprehensive services are available achieve greater reductions in use ([Yancovitz et al., 1991](#); [McLellan, 1993](#)).

Concerns about interim therapy have been raised, especially if it is seen by providers and managed care companies as a less expensive and equally effective model for the treatment of opiate dependence. Interim therapy should never be viewed as an alternative to comprehensive opioid substitution therapy programs.

Engaging this patient population in continued care has significant public health implications. Not only can these patients receive treatment for HIV disease and its complications, but they also can receive counseling about the disease and about behavioral changes that will reduce the risk of HIV transmission.

The Need for Resources

Meeting patients' needs in opioid substitution therapy cannot be addressed without looking at the cost benefits of providing comprehensive services to opioid-dependent patients. These are often persons with no readily available entry point into the healthcare system, and methadone treatment programs often provide an entry. Therefore, appropriate decisions about what services are needed, for how long, and in what setting are crucial. As described above, untreated addicted patients meet their healthcare needs in a crisis-oriented episodic fashion -- by utilizing emergency services as their primary care provider. Implementation of comprehensive outpatient models providing long-term care decreases the high utilization of more expensive acute care services.

Many programs are not able to afford comprehensive services for patients entering opioid substitution therapy. Therefore, programs must develop other models for effective services. One option is to develop linkages or networks between services and to refer patients to offsite services, thus attempting to contain costs while providing necessary services. Unfortunately, because of the fragmented system of publicly funded healthcare, public ambivalence about treating persons with opioid dependence, and extremely restricted resources in the public outpatient treatment area, many programs have great difficulty or even find it impossible to establish these liaisons. In these cases, programs must do the best they can and hope for improvements in service delivery that will make meaningful, comprehensive treatment possible.

As discussed earlier in this chapter, the potential financial advantages to managed care companies from combining psychiatric and medical services with substance abuse treatment may change this situation. Treatment providers and taxpayers could benefit from serious efforts to combine these important services and realize the cost savings that may result.

Recent Federal block grant requirements have created a mandatory link between the provision of substance abuse treatment and other healthcare services for pregnant and parenting women, persons from minority groups, individuals with dual diagnoses, injection drug users, disabled

persons, HIV-infected persons, and persons with TB. While not designed specifically for opioid substitution therapy, these requirements must be met by all programs receiving Federal funding under the State block grant mechanisms. Now being implemented, the regulations are particularly important for State AOD directors who must determine how to establish the mandated links. These requirements may encourage States, HMOs, managed care companies, and other healthcare providers to increase their efforts to develop the treatment resources that will make matching strategies more of a reality than they are at present. Many of these aims can be achieved through networking.

Examples of Networking

Effective networking should cut across several disciplines. Some examples of networking are described below:

- Contact with State and city public health, mental health, and vocational rehabilitation departments.
- Creation of ad hoc alliances. For example, under the Yale/New Haven Model, a methadone treatment program became allied with the mayor's task force to create a women's health consortium. The consortium established a referral network through which each client had two counselors, one for methadone treatment and one for other health, mental health, and ancillary needs.
- Access to services supported by the Federal Government, including clearinghouses, electronic databases, and training and technical assistance programs.
- Access to programs for special populations, including abused children, victims of domestic violence, the homeless, and persons with disabilities.
- Use of pro bono legal services.
- Establishment of relationships with health, mental health, and civil rights advocacy groups.
- Use of educational, training, and technical assistance resources available through professional organizations.

Equally important is the development of a proactive attitude toward community outreach. For example, program staff might seek opportunities to sit on the boards of directors of other agencies and organizations, and members of these organizations might be invited to join the opioid substitution program board. Such relationships broaden understanding of individual and shared program goals and increase the likelihood of appropriate referrals. Given the multiplicity of patient needs and limited resources, "turfism" and insularity are ill advised.

In addition to providing concrete services, networking can create a feeling of shared responsibility for patient welfare. It also increases program visibility and broadens public understanding of the purpose of opioid substitution therapy and its role in substance abuse treatment and rehabilitation.

Optimizing Methadone Treatment Outcome: The Challenges

Persons who are addicted to opioids share many of the problems and needs of those with other substance use disorders. At the same time, opioid-addicted persons present unique treatment

challenges. The CSAT consensus panel believes that the following five challenges are especially important.

Challenge 1: Understanding That Opiate Addiction Is a Chronic, Relapsing Disorder

Among the most important factors to be understood when assessing the progress of an opioid-addicted patient is the probability of relapse, or recurrence of opioid use. Posttreatment followup studies have shown that roughly 80 percent of all patients resume daily use of opioids within the first year of leaving treatment ([Ball and Ross, 1991](#); [Hubbard and Marsden, 1986](#); [Simpson and Marsh, 1986](#)). However, it has also been shown that relapses may lead to a series of readmissions that are eventually associated with successive reductions in drug use and even extended periods of remission ([Simpson and Savage, 1980](#)). A 12-year followup study of 490 opioid-addicted patients treated in the Drug Abuse Reporting Program showed that each patient averaged more than six AOD treatment admissions. However, improvement occurred over time, and only one patient in four was still using opiates in the year preceding the last followup interview ([Marsh et al., 1990](#)).

Even patients who are highly motivated to achieve total abstinence and who terminate treatment under the best of circumstances have a less than 50 percent chance of remaining in full remission for as long as 3 years ([Hargreaves, 1983](#)). Such surveys substantiate the General Accounting Office conclusion that heroin addiction is a chronic, relapsing condition that many persons "will battle the rest of their lives" ([General Accounting Office, 1990](#)).

Relapses are, in other words, a predictable part of opioid addiction. The number of relapses does not predict failure in treatment; in fact, past relapses correlate positively with ultimate treatment success, and resistance to relapse increases as long-term abstinence increases ([Simpson and Marsh, 1986](#)).

Studies that explore additional predictors of treatment outcome have shown that patients who are older, have a stable family and an intact marriage, and are employed are more likely to have positive results than younger, unemployed patients with less stable family support.

Polydrug and alcohol abuse, psychopathology, and a history of criminal activity that is independent of the substance use disorder are associated with poorer treatment outcomes ([Anglin and Hser, 1990](#); [McLellan, 1986](#)).

Challenge 2: Providing Comprehensive Services to Ensure Successful Opioid Substitution Therapy

Substitution therapy often has been mistakenly perceived as a simple and inexpensive pharmacologic treatment for opioid addiction. On the contrary, most patients who enter opioid substitution therapy have multiple needs and the most effective programs provide comprehensive services to meet these needs ([Anglin and Hser, 1990](#); [Ball and Ross, 1991](#); [Joe et al., 1991](#)). One recent study has shown that 85 percent of patients entering methadone treatment had problems in more than one of the following areas: physical or mental health; family and peer relationships; and legal, educational, vocational, and financial matters.

Unfortunately, because of 1) the fragmented system of publicly-funded healthcare, 2) public ambivalence about treating persons with opioid dependence, and 3) extremely restricted resources in the public outpatient treatment area, many programs have great difficulty or even find it impossible to establish liaisons with other agencies to provide needed services.

Although most patients' needs were in more than one of these areas, only 25 percent reported receiving any medical, psychiatric, or social services during the critical first month of treatment ([Condelli, 1993](#)). The role of ancillary services in improving treatment outcome is illustrated in studies such as that of [McLellan et al. \(1993\)](#), who documented an improvement in AOD treatment outcomes associated with provision of appropriate psychosocial services to methadone patients. As discussed in later chapters of this TIP, some patients require assistance in gaining access to and utilizing needed services. An addictions counselor or case manager often performs this function.

Challenge 3: Engaging and Retaining the Patient in Treatment

Length of time in treatment is one of the most consistent indicators of positive treatment outcomes. It has repeatedly been shown to be associated with reduced use of opioids and other drugs, greater productivity, and reduced criminal activity ([Ball and Ross, 1991](#); [D'Aunno and Vaughn, 1992](#); [General Accounting Office, 1990](#); [Simpson and Sells, 1982](#)). A minimum of 3 months in treatment is usually necessary before progress toward recovery begins ([Simpson and Sells, 1982](#)).

Retention is thus a primary objective of treatment, and the challenge to the clinical team is to take every reasonable action to keep the patient actively engaged. Several investigators have sought to determine the factors most likely to be associated with retention. Among these are comprehensive and individualized services, caring staff, "user friendly" program protocols, and an adequate methadone dosage ([Condelli, 1993](#); [Joe et al., 1991](#)).

To promote retention, patients should be engaged in treatment and participate actively in the therapeutic process. More frequent attendance, compliance with psychiatric services, and use of other ancillary services are associated with improved treatment outcomes ([McLellan et al., 1993](#); [Simpson et al., 1995](#)). Thus, augmenting program resources and encouraging their use should be prime concerns of program staff. One recent study found that elimination of treatment fees increased retention during the first year of treatment ([Maddux et al., 1994](#)). Consideration also should be given to developing techniques for monitoring service delivery and levels of patient engagement over time (see [Chapter 5](#) on program evaluation). As is discussed later in this TIP, case managers can play an important role in retaining patients in treatment by ensuring that they gain access to and use needed services.

Factors most likely to be associated with retention in treatment are comprehensive and individualized services, caring staff, "user friendly" program protocols, and an adequate methadone dosage.

Challenge 4: Managing Patient Noncompliance in a Positive Manner

Recent research has deepened understanding of the contribution of patient motivation and readiness for change to positive outcome in persons with AOD disorders ([Miller and Rollnick, 1991](#); [Prochaska and DiClemente, 1986](#)). For this reason, it is important to explore patient motivation at the time of assessment and throughout treatment. Most patients are initially ambivalent about treatment, and clinicians must help them resolve this ambivalence. Many patients may have attitudes or experiences that create obstacles to engaging in treatment. For example, some patients have the fixed notion that only methadone will work for them and that methadone is all they need. Others may not want to participate in 12-step programs because of negative past experiences with persons in those programs who rejected opioid substitution therapy. Some patients may resist medical care because healthcare providers in the past have reacted negatively to their addiction and its associated behavior.

Clinicians must be prepared to identify and overcome these obstacles. They also must be prepared to clarify and negotiate mutually acceptable treatment goals. The more committed patients are to their treatment goals, the more likely they are to remain in the program and have a positive outcome ([Simpson and Joe, 1993](#)).

Patient noncompliance -- whether it manifests as a deviation from an individual treatment plan or as a violation of program rules -- should be seen not only as a sign of potentially poor outcome, but also as an indication of possible problems in the treatment plan. Providers should continually review and examine their delivery of services before "blaming" the patient for not complying with treatment. Program staff must be alert to subtle attitudinal changes of patients and be prepared to address those attitudes even before problems stemming from noncompliance arise and interfere with treatment. The reasons underlying a loss of motivation or ambivalence about treatment goals should be promptly explored and resolved, if possible, with the objective of making the treatment plan more realistic. For example, a patient's response to a brief relapse to opioid use could lead to discouragement and premature termination if the staff did not encourage and educate the patient about the realistic course of addiction treatment.

Challenge 5: Expanding Community Awareness of the Purpose and Outcome of Opioid Substitution Therapy

Clinicians who provide opioid substitution therapy must create opportunities to educate the community, including the public, legislators, and third-party payers, about the nature of opiate addiction, its anticipated outcomes, and the benefits of treatment. Methadone is commonly seen as a "chemical crutch," and opioid substitution therapy is viewed as replacing one drug with another. Added to such philosophical and ideological reservations may be fears of public and personal safety stemming from drug sales or clients' loitering in neighborhoods where opioid substitution therapy programs are located.

Treatment program staff must make efforts to overcome misconceptions concerning opioid addiction and inform the public about the entire range of treatment options and the overall positive benefits of opioid substitution therapy. They can do this through networking, public education (giving examples of patients who were helped by substitution therapy), and outreach.

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Organization of This TIP

This TIP provides guidelines for meeting patient needs in opioid substitution therapy. It takes into consideration the needs of patients, limited resources, the current knowledge base, and outcome evaluation.

[Chapter 2](#) *Assessing Patient Needs* provides a brief overview of opioid substitution therapy and definitions of terms used in the TIP. Guidelines are offered for conducting both a preliminary assessment to determine a person's appropriateness for substitution therapy and a comprehensive biopsychosocial assessment upon entry into the program. Areas to assess are recommended, including the patient's expectations and motivation. Effective matching depends on careful ongoing assessment, which is also discussed.

[Chapter 3](#) *Phases of Treatment* proposes a six-phase model of opioid substitution therapy that includes the acute and rehabilitation phases, the supportive care phase, medical maintenance, tapering and readjustment, and aftercare. Patient needs characteristic of each phase are described, and strategies for meeting these needs are outlined. Clinical indicators for transition into other treatment phases are described.

[Chapter 4](#) *Treatment Elements* looks at core services essential for opioid substitution therapy programs and the responsibilities of staff from various disciplines who facilitate the use of treatment matching strategies in these programs. Common comorbid medical and psychiatric disorders are discussed and the roles of counseling and psychotherapy are summarized. Special considerations, such as childcare and access for disabled persons, are addressed.

[Chapter 5](#) *Self-Monitoring and Evaluation* addresses the importance of program self-monitoring and evaluation of treatment outcomes. Goals of these processes are outlined, and a step-by-step guide for conducting self-monitoring and evaluation is presented. A detailed hypothetical example is included in an easy-to-follow chart format that lays out the evaluation steps described in the text.

[Chapter 6](#) *Cost-Effectiveness of Opioid Substitution Therapy* addresses the costs of opioid substitution therapy services and describes approaches to calculating treatment costs.

[Appendix A](#), lists references cited in the text, as well as other useful articles. [Appendix B](#) contains the Massachusetts Methadone Treatment Criteria, which were modeled on the American Society of Addiction Medicine patient placement criteria ([American Society of Addiction Medicine, 1991](#)). They provide admission, continuing care, and discharge criteria for AOD abuse treatment including methadone substitution therapy. For readers who are interested in designing and conducting research on the costs of AOD treatment, [Appendix C](#) presents several methodological approaches to consider. [Appendix D](#) is a list of the Federal resource panel members who contributed suggestions during the initial phases of the development of this TIP. [Appendix E](#) is a list of experts who participated in the field review of the TIP.

Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series 20

Chapter 2 -- Assessing Patient Needs

This chapter begins with an overview of the goals of opioid substitution therapy and discusses the importance of identifying patients' individual needs. Also included is a brief description of several treatment courses available to patients over the course of opioid substitution therapy. Definitions of terms used throughout this Treatment Improvement Protocol (TIP) are presented.

The main focus of this chapter is to describe both an initial assessment, to determine whether a patient is appropriate for admission to an opioid substitution therapy program, and a comprehensive assessment, to identify a patient's individual needs after program entry. Areas included in each assessment are presented, along with procedures to maintain an ongoing assessment of patients' progress in treatment.

Opioid substitution therapy is appropriate for persons with chronic opioid dependence and addiction who have a history of repeated relapse, persons who live in environments that do not support a life-style free of substance use, and those who repeatedly engage in criminal behavior related to their chronic opioid use.

Opioid Substitution Therapy

Treatment Goals and Admission Criteria

The goals of opioid substitution therapy guide the development of a treatment system and form the foundation for the type, intensity, and elements of treatment services necessary to meet patient needs. The major components necessary to meet the goals of substitution therapy include either methadone or levo-alpha-acetyl methadol (LAAM), rehabilitative services, and support services. The primary goals of treatment are highly dependent on the specific population being treated; however, the general goals of opioid substitution therapy are

- To eliminate objective signs and subjective symptoms of opiate withdrawal
- To decrease craving for opioids
- To decrease or eliminate injection drug use
- To reduce inappropriate nonopioid drug use and dependence

- To improve health and encourage patient to establish a relationship with a primary care clinician
- To decrease other human immunodeficiency virus (HIV) high-risk behaviors
- To decrease or eliminate criminal activity
- To improve mental health and well-being
- To increase psychosocial supports
- To improve psychosocial functioning, including ability to gain or maintain employment.

Opioid substitution therapy is appropriate for persons with chronic opiate dependence (addiction) who have a history of repeated relapse, persons who live in environments that do not support a lifestyle free of substance use, and persons who repeatedly engage in criminal behavior related to their chronic opiate use. Criteria used to determine appropriateness include history of substance use, physical examination results, results of laboratory tests (blood and urine), Food and Drug Administration (FDA) admission criteria, and patient preference. Persons who are considered high-priority candidates for admission include

- Pregnant opioid-dependent patients
- Patients at high risk of HIV infection
- Patients with life-threatening diseases, such as tuberculosis, that are made worse by injection drug use
- Patients with serious endocarditis and septic arthritis
- Patients receiving Interferon for hepatitis C.

Many of the basic elements of matching opioid-addicted patients to opioid substitution therapy are presented in FDA guidelines, 21 C.F.R Part 291 § 291.501, § 291.505 (1993), as well as in applicable State regulations. These documents discuss minimal standards for entry into treatment, continuing care, and discharge. The regulations are reprinted in another TIP, *State Methadone Treatment Guidelines*.

Patient Needs

Matching patients to treatment services is critical to the successful engagement of patients in the treatment process. Not all patients need the same type or intensity of service. People in some population groups have special needs that, if not addressed, become barriers to treatment. For example, women may have gender-related and psychosocial issues such as emotional, physical, and sexual abuse that may make them uncomfortable in male-dominated treatment programs. Further, pregnant or parenting women may have needs for childcare and other services such as transportation that, if not addressed, would interfere with attending treatment. Homeless patients need housing. Patients and their families from certain ethnic and cultural backgrounds may have religious or cultural beliefs about drug and alcohol use that affect their goals and use of treatment.

Matching patients to treatment services is critical to the successful engagement of patients in the treatment process. Not all patients need the same type or intensity of service. Patients from certain

ethnic and cultural backgrounds may have religious or cultural beliefs about drug and alcohol use that affect their use of treatment.

Patients with health problems and those who are at risk of exposure to life-threatening illnesses represent another group with special needs. Providing access to a full range of medical care services is critical for successful treatment outcomes. Services should address risk factors for HIV and other sexually transmitted diseases, opportunistic infections, and tuberculosis (TB). Many patients in opioid substitution therapy need assistance to gain access to social and family services. Easily accessible services for patients with physical disabilities, chronic pain, and mental illness are necessary to support successful treatment.

A large percentage of patients who are appropriate for opioid substitution therapy either abuse or are dependent on other substances, such as cocaine, alcohol, and benzodiazepines. Opioid substitution therapy programs must address these treatment needs while focusing on the patient's primary dependence on opiates. (A separate TIP in this series, *Screening, Assessment, and Treatment Planning for Patients With Dual Dependency on Opioids and Stimulants*, provides guidelines for treating dependence on other substances.) Outpatient and inpatient detoxification programs should allow continued methadone maintenance while patients are being detoxified from other drugs followed by referral back to the methadone program. For patients whose environments do not support their recovery, residential treatment and half-way houses can provide elements of successful treatment.

Many patients in opioid substitution therapy need educational and vocational training. Needs range from those of patients who have not completed a high school level of education and who have varying degrees of literacy and little or no licit work history, to those of patients who are college educated with a history of successful employment. Obtaining or maintaining work is an important component of the treatment process. Whether this means they need help in developing appropriate parenting skills, completing an educational program, or pursuing employment, patients entering opioid substitution therapy need structure in their lives to make the changes necessary for recovery.

It is important to perform an assessment of the patient's educational background and employment history to plan an effective treatment experience. A brief history should be taken at admission, followed by a more comprehensive assessment once the patient is stabilized in a treatment program. Resources vary in opioid substitution programs. Some programs offer vocational counseling within programs, others develop affiliation agreements with agencies that can offer these services. Regardless of the model, identifying vocational and educational needs and matching patients to the appropriate resources are important parts of the rehabilitative and habilitative process.

The Setting and Course of Treatment

Opioid substitution therapy is usually offered in a traditional outpatient model, a narcotic treatment program approved by Federal and State authorities. For the most part, patients with

chronic opioid dependence and addiction receive methadone maintenance treatment in this setting. As treatment needs become clearer and the multiplicity of their medical, psychological, social, and behavioral needs becomes evident, a full continuum of care for these patients emerges as an important contributor to a positive outcome.

Some opioid substitution therapy programs are part of a continuum of substance abuse treatment programs that includes therapeutic communities, inpatient detoxification units, day treatment, and outpatient counseling programs. Others may also be part of a mental health center. Programs that are part of a continuum of substance abuse and mental health services may have a centralized intake unit that operates as the central assessment component for all the treatment programs. The central unit places the patient in more than one program according to the patient's multiple needs. For example, if a patient is eligible for opioid substitution therapy and needs the environmental containment of a therapeutic community, placement can meet both of these needs. Similarly, if a patient appropriate for substitution therapy also needs psychiatric care, both services can be accessed. Although the programs that provide such multiple placement are rare, it is important to meet the multiple needs of patients. Regardless of the model, a clear assessment of needs is the beginning of setting the course of treatment for the patient.

Patients who enter opioid substitution therapy may eventually take several different treatment courses. Some may leave methadone treatment through medically supervised withdrawal (detoxification) and then continue in drug-free treatment. Medically supervised withdrawal is accomplished in an inpatient unit or outpatient methadone treatment program, and continued therapy involves outpatient or residential treatment, with or without the use of antagonist (naltrexone) treatment. Patients who do not remain opioid free can typically reenter opioid substitution therapy with the goal of eventually becoming drug free. Some may succeed in this goal, while others will need to remain in substitution therapy.

Some patients substantially reduce their use of opioids and need continued maintenance treatment to maintain this reduction in opioid use. However, they may require the containment and support of a residential treatment environment to address alcohol and nonopioid drug use and dependence. These patients will continue on methadone during inpatient treatment for other drug and alcohol abuse. Upon completion of inpatient treatment, they can return to outpatient treatment to continue methadone treatment.

A challenge remains. As mentioned in [Chapter 1](#), continued methadone maintenance during withdrawal from alcohol or other drugs is not always available within the addiction treatment community. Opioid substitution therapy programs must work with licensing bodies and State agencies to provide education and advocacy for these services. In some cases, treatment programs must review and revise their philosophy and policies to meet the needs of patients.

Others need continued opioid substitution therapy with an emphasis on treatment of comorbid medical and psychiatric problems. Providing opioid substitution therapy in a variety of treatment settings is necessary to meet the needs of these patients. Although some States, programs, and hospitals take a multiple-problem treatment approach, access to these additional services is not universal, and changes in the system are critical for efficacious treatment.

Continued methadone maintenance during withdrawal from alcohol or other drugs is not always available within the addiction treatment community. Opioid substitution therapy programs must work with licensing bodies and State agencies to provide education and advocacy for these services.

Medically Supervised Withdrawal From Methadone

As discussed more fully in [Chapter 3](#), careful consideration must be given to when and how withdrawal from methadone is done and what patients are appropriate for this step. The goal of voluntary withdrawal (or tapering) from methadone should be for the patient to become drug free. A patient who is being voluntarily withdrawn from methadone and who is progressively resuming illicit drug use should be strongly discouraged from completing the withdrawal process.

Age, as well as patient preferences and beliefs about the safety and side effects of methadone treatment, should be considered in decisions to withdraw from methadone. Risk of relapse after detoxification and appropriate followup treatment should also be taken into account. Should withdrawal from methadone or LAAM be accomplished on an inpatient or outpatient basis? How quickly should it occur, and from what dose? Does the patient have other medical or psychiatric needs that would affect this decision? Is the patient pregnant? Is withdrawal voluntary or involuntary? These issues must be considered to match patients to these services. Another TIP in this series, *Detoxification From Alcohol and Other Drugs* (in development), addresses special issues in medically supervised withdrawal, including tapering, from methadone.

Definitions

The term *opiate* refers to opium and derivatives of opium, a naturally occurring substance, that have effects similar to those of morphine. Heroin, codeine, and morphine are examples of opiates. The term *opioid* refers to all substances, both those derived from opium and those synthetically produced, that have effects similar to morphine. Examples of opioids include heroin and codeine, which are natural derivatives of opiates, and Demerol, Percodan, and methadone, which are synthetics. The more inclusive term *opioid* is used throughout this TIP. *Narcotic* is the term that was formerly used as a synonym for *opiate*; it is currently a synonym for *opioid*. Use of narcotic has been avoided in this TIP in favor of *opioid*.

Both *agonist* and *antagonist* agents have been used for treating opioid addiction. An *agonist* agent is a drug with properties very similar to those of another drug, usually from the same drug class. Methadone is a narcotic agonist, since it has many effects that are similar to morphine. An *antagonist* is an agent that blocks or reverses the effects of another drug. Naltrexone is an opioid antagonist because it blocks or reverses the effects of opioids like morphine, methadone, and other drugs with similar properties.

The term opioid refers to all substances, both those derived from opium (opiates) and those synthetically produced, that have effects similar to morphine. The more inclusive term opioid is used throughout this TIP.

Naltrexone is also used to treat opioid-addicted persons, but only with their permission or after they have been detoxified. Giving naltrexone to someone receiving methadone or LAAM who has not been withdrawn will cause a severe opioid withdrawal reaction that could be life threatening for some patients with concurrent medical problems (for example, hypertension and diabetes) since it reverses all opioid agonist effects of the methadone or LAAM and precipitously induces a withdrawal syndrome.

Use, Abuse, and Dependence: Evolution of Concepts and Terms

Three terms are often applied to the self-administration of abusable substances: *use*, *abuse*, and *dependence*. Only the latter two -- abuse and dependence -- are psychiatric disorders that justify treatment. Use in the absence of abuse or dependence is a psychosocial phenomenon that may or may not lead to abuse or dependence. Although use of abusable substances often requires attention, simple use of a substance does not qualify a person for formal treatment. However, use of substances by persons with a history of a substance use disorder may be a sign of a recurrence of the disorder.

The definitions of *abuse* and *dependence* have changed over the last 20 years, and as a result, there is often confusion about what is meant by *dependence* or *addiction*. The American Psychiatric Association publishes a manual that is widely used to diagnose mental and substance use disorders. In the third edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-III), published in 1983, *dependence* applied to persons with pathological patterns of abuse who also had developed tolerance and withdrawal, while *abuse* consisted only of a pathological pattern of use. In DSM-III, *physiological dependence* was the defining feature of dependence.

The World Health Organization also publishes a diagnostic and classification manual of diseases and disorders, the *International Classification of Diseases* (ICD). In recent years, the World Health Organization and the American Psychiatric Association have made a serious effort to make their criteria, including those for identifying substance use disorders, as similar as possible. One of the problems that arose as a consequence of the emphasis that the DSM-III placed on tolerance and withdrawal was that persons who had become physiologically dependent on a substance through the course of legitimate medical treatment (for example, taking opioids as prescribed for treatment of chronic pain) were classified as drug dependent. Many persons saw this classification as misplaced, primarily because the type of dependence seen in medical and surgical patients is usually different from that of persons who seek out and compulsively use substances for nonmedical reasons.

Additionally, in DSM-III there was significant overlap between the criteria for dependence and abuse. The only clear distinction between these two disorders was the presence or absence of

tolerance or withdrawal. Based on the criteria, it was unclear whether abuse was a less severe form of dependence or if it represented a different disorder with a different course and prognosis.

With the revised version of the DSM-III, published in 1987 and referred to as the DSM-III-R, the definition of dependence was significantly changed. This definition reflected changes in views that had already been incorporated in the ICD-9 (ninth edition), published in 1977. The DSM-III-R criteria indicated a shift away from the physiological to the behavioral elements of dependence. Behavioral components indicating compulsive use and loss of control over use were emphasized. In DSM-III-R, tolerance and withdrawal continued to be important features of dependence, but they were not the defining features and were not necessary for making a diagnosis of dependence. Persons could be diagnosed with substance dependence if three or more of the nine criteria could be applied. Only three of the criteria related to tolerance or withdrawal. Abuse was a residual category, defined as a maladaptive pattern of problematic use in which compulsive use, tolerance, and withdrawal were not prominent.

The shift in focus toward behavioral elements of dependence reflected growing recognition of a definable and independent syndrome that could result after an organism learned to self-administer abusable substances. This syndrome was not dependent upon the ability of the substance to produce tolerance and withdrawal, but rather on its positive reinforcing effects. Thus, the DSM-III-R clarified the distinction between prescribed drug use by medical, surgical, or psychiatric patients that is accompanied by tolerance or withdrawal and dependence. It also developed criteria that applied to dependence on cocaine and other substances that do not always cause prominent withdrawal. In doing so, DSM-III-R significantly broadened the definition of dependence and increased the number of persons with this diagnosis.

The most recent version of the manual, DSM-IV (American Psychiatric Association, 1994), continues the emphasis on compulsive use and loss of control as the defining features of dependence ([see Exhibit 2-1](#)). The criteria items were modified slightly, and the number of criteria describing dependence was reduced from nine to seven. One of the criteria continues to be tolerance and another withdrawal. Dependence is diagnosed if three or more criteria can be applied to a patient; dependence is subtyped as being with or without physiological features, depending upon whether tolerance, withdrawal, or both are present.

The major change in DSM-IV was in the definition of abuse. Criteria for abuse were clearly separated from those for dependence. This change was accomplished by identifying as abuse only items that signify problematic or hazardous use. Items that signify compulsive use, tolerance, or withdrawal are criteria of dependence.

ICD-10, the latest version, published in 1992, no longer separates drug and alcohol dependence; they are merged into a single dependence syndrome that is applied to all substances. ICD-10 has six criteria for dependence ([see Exhibit 2-2](#)). As in DSM-IV, a person must meet three or more to be diagnosed as dependent. ICD-10 does not have a category called "abuse." Instead, the category of "hazardous use" described in ICD-9 was changed to "harmful use." *Harmful use* is defined as a pattern of psychoactive substance use that causes damage to health. The damage may be physical (for example, hepatitis resulting from injection drug use) or mental (for example, episodes of depressive disorder secondary to heavy consumption of alcohol).

In this TIP, the term *addiction* is frequently used to describe patients with opioid dependence who are appropriate candidates for substitution therapy. Although these individuals generally meet the criteria for opioid *dependence* as described in DSM-III-R or DSM-IV, the term addiction, rather than dependence, is often used in this TIP because it is commonly used in the field. In DSM-III-R or DSM-IV terms, *addiction* as used here describes someone who meets three or more of the items for dependence, including criterion item 1 (tolerance) and item 2 (withdrawal). Thus, in DSM-IV terms, someone with addiction is classified as having dependence, with physiological features.

Persons who have developed physiological adaptation to chronic opioid use as a consequence of pain treatment -- even though they exhibit tolerance and withdrawal -- are to be distinguished from *opioid-addicted persons* as the term is used here, unless they also develop signs and symptoms of compulsive use and loss of control. They typically do not need the structure and drug-focused therapy that are part of an opioid substitution treatment program and should not be confused with persons who have an *addiction* simply because they share some of the symptoms.

The Preliminary Assessment: Determining Eligibility for Opioid Substitution Therapy

Despite myriad regulations governing opioid substitution therapy, little attention is given to the quality of services and to the clinical judgments that are critical in matching patients to the most appropriate treatment. Matching begins with the preliminary assessment, which may take place in a variety of settings. Common locations are hospital emergency rooms and central intake units; however, the final assessment of eligibility for opioid substitution therapy must be completed by the treatment program staff.

The primary purpose of the preliminary assessment is to determine whether an individual is eligible for entry into opioid substitution therapy and whether such treatment would be appropriate for that person. The preliminary assessment should include five areas:

- Determining the need for emergency care
- Diagnosing the presence and severity of opioid dependence
- Determining the extent of alcohol and other drug (AOD) abuse
- Screening for medical and psychiatric comorbid conditions
- Evaluating the individual's living situation, family and social problems, and legal problems.

The Need for Emergency Care

Any patient who has an acute or severe medical problem, who is suicidal or psychotic, or who exhibits other symptoms that jeopardize his or her safety or that of others must be referred immediately for inpatient medical or psychiatric care. Persons doing the initial assessment should rule out such conditions before referral for outpatient substitution therapy.

Presence of Opioid Dependence

Federal guidelines restrict entry into methadone programs to individuals who have been dependent on opioids for the better part of the year prior to application for admission and who manifest symptoms of physical dependence on opioids. Pregnant women who are opiate dependent and persons released from an institutional environment who are on the verge of relapse are exempted from the rule regarding 1-year duration of opioid dependence (see details in FDA regulations reprinted in the TIP *State Methadone Treatment Guidelines*). Criteria for diagnosing psychoactive substance dependence, such as those set forth in the DSM-IV or the ICD-10, should be used to assess the presence of opioid dependence. It should be noted that, although such criteria are useful, Federal regulations do not specify a DSM-IV or ICD-10 diagnosis of opioid dependence for admission to opioid substitution therapy, although such a diagnosis is required *de facto*, according to the way the regulations are written.

When applying criteria during the preliminary assessment of a person who uses opioids, the clinician must give special attention to several areas. Individuals who use opioids only occasionally, who can control their use, and who are not physically dependent are not appropriate candidates for opioid substitution therapy unless they meet the special conditions defined below ([Zinberg and Harding, 1982](#); [Zinberg et al., 1981](#)). Given the wide variations in patterns of heroin and other opioid use, it is helpful to begin the preliminary assessment by reviewing these broad distinctions.

To determine whether a prospective patient meets Federal requirements, one must secure a complete history of the patient's drug use, focusing on the length of time that opioids have been used, the quantity and type of drugs used, the route of administration, and physical signs and symptoms of dependence. Application of diagnostic criteria will elicit information on intensity, duration, and pattern of use that is needed to establish the presence of dependence. Pattern of use is especially important because it is a subtler and potentially more revealing indicator of problems than duration or intensity of use alone. Determination of opioid dependence is discussed in more detail in the section in this chapter on The Medical Assessment.

If the patient's reported drug history and physical examination are inadequate to substantiate a diagnosis of chronic opioid dependence, it may be necessary to gather data from outpatient observation, with a more extended assessment, or from material submitted by other medical and healthcare professionals, family members, a legal guardian, or a significant other.

A patient may insist he or she is addicted, but the clinician may remain uncertain. In these cases, it is appropriate to administer a naloxone (Narcan) challenge test. The patient is administered slowly .4 or .8 mg of naloxone intramuscularly or intravenously. If physical dependence on opioids is present, the patient will develop opioid withdrawal symptoms within 30 to 60 seconds if naloxone is given intravenously, or within 2 to 5 minutes if it is given intramuscularly. If withdrawal does not occur, the person is not physically dependent and probably does not qualify for opioid substitution therapy. If the naloxone test is positive, withdrawal symptoms can be marked; however, since naloxone is a short-acting drug, they disappear within 30 to 60 minutes. The Narcan challenge is inappropriate for certain individuals; it should not be used with pregnant women or with persons who have heart disease.

Adolescents

The majority of adolescents drink alcohol, but the use of marijuana, cocaine, and crack, as well as tranquilizers and sedatives, is also prevalent and varies with geographic location. Opiate use is less common. In a 1983 national survey, only 6 percent of senior high school students reported ever using opioids; opioid use, when it occurs, usually comes later in the use progression ([Johnson et al., 1984](#)). For the most part, adolescents who come to treatment programs are heavily involved in substance use and may use alcohol or drugs daily. They tend to have started drug use at an early age, have endured many negative experiences within a brief span of time, and have problems functioning at home and in school.

Although assessment is similar in many ways for adolescents and adults, an adolescent's age, psychosocial development, environment, and family supports are critical factors in assessing opioid dependence.

Adolescence marks a time of great physical, social, cognitive, psychological, and emotional changes. Struggling to cope with these changes can stir up feelings of powerlessness, alienation, and rebellion. Adolescents often assess their emotions and behaviors by the reaction of their peers and are highly vulnerable to the influence of their peer group. Therefore, experimentation and recreational use of drugs are common, often associated with pleasure and euphoria, and not perceived as bad or dangerous ([Dusenbury et al., 1992](#)).

Although assessment is similar in many ways for adolescents and adults, an adolescent's age, psychosocial development, environment, and family supports are critical factors in assessing opioid dependence. (Another TIP in this series, *Screening and Assessment of Alcohol- and Other Drug-Abusing Adolescents*, addresses issues unique to adolescents.) Most adolescents who use opioids sniff or snort heroin; few inject. Some have access to opioids from physicians for treatment of menstrual pain or migraine headaches. These issues should all be considered in the assessment process.

A range and variety of drug treatment programs are available for adolescents. Opioid substitution therapy may be considered for adolescents, but admission depends on the patient's having tried and failed two prior treatment interventions before he or she is eligible for admission. Most methadone treatment programs do not accept patients unless they are over 18 years old, but admission is possible for patients under 18 with parental consent. When exploring the option of opioid substitution therapy for an adolescent, careful consideration should be given to referral to programs that specialize in the treatment of heroin addiction in this age group. The Adolescent Development Program in New York City has developed such a program, which could serve as a model for others ([Millman et al., 1978](#)).

Extent of AOD Use

From 30 to 70 percent of opioid-dependent patients use other drugs. The most common AOD use disorders among opioid users involve cocaine, benzodiazepines, and alcohol. A recent study estimated that up to 75 percent of persons being treated in methadone programs might be abusing cocaine ([Avants et al., 1994](#)). Nicotine dependence is also extremely prevalent. Marijuana use is common, and some patients seek treatment for marijuana abuse or dependence. Abuse of alcohol and drugs other than opioids creates major life problems among patients in methadone treatment. A urine toxicological screening test is very helpful in documenting current opioid use and identifying other substances being used. It is critical to note that, unlike withdrawal from opioids, withdrawal from alcohol and sedatives can be life threatening.

The most common AOD use disorders among opioid users involve cocaine, benzodiazepines, and alcohol. A recent study estimated that up to 75 percent of persons being treated in methadone programs might be abusing cocaine.

Results of urine, breath, or blood tests are only one consideration for determining appropriateness for opioid substitution therapy. No patient should automatically be excluded from substitution therapy because he or she has a positive test for (or uses) other drugs. One essential purpose of the preliminary assessment is to identify individuals whose AOD use is so out of control that they are physically dependent. Another purpose is to determine if they need detoxification from other drugs or other inpatient treatments before opioid substitution therapy may begin. For example, a patient who uses benzodiazepines but is otherwise stable may enter opioid substitution therapy immediately. However, an individual whose use of benzodiazepines cannot be controlled may have to be detoxified from benzodiazepines before admission to an opioid substitution therapy program. Hospitalization may not be available in some cases, and it should not be required for entry into an opioid substitution therapy program. For programs with adequate medical staff, medically supervised outpatient detoxification from benzodiazepines is an option.

Comorbid Conditions

Medical Conditions

A number of comorbid medical conditions are relatively common among opioid users. They include cellulitis, tuberculosis (TB), HIV infection, hepatitis (A, B, C, and D), cirrhosis, and syphilis and other sexually transmitted diseases (STDs). In some communities, more than 50 percent of injection drug users are HIV infected. TB is a growing problem among substance abusers, and almost half of the patients in some treatment programs have positive tuberculin skin tests. HIV-infected opioid addicts who become infected with TB are significant contributors to the increasing prevalence of TB and to the emergence of antibiotic-resistant strains of the tubercle bacillus.

Many programs report that 90 percent or more of their patients test positive for infection with the hepatitis C virus. This problem is only recently becoming well documented and is extremely serious because mortality rates can be as high as 20 percent over the long-term course of the disease. Hepatitis C infection probably explains the mild to moderate elevations in liver function tests that are commonly observed among opioid addicts. Identification of this viral infection is important from a treatment standpoint because Interferon has been shown to be effective in suppressing the progress of hepatitis C infection in 20 percent of cases.

Other common medical conditions among opioid addicts are related to the effects of a chaotic lifestyle or the use of other abused substances. These conditions include nutritional deficiencies and anemia caused by poor eating habits, chronic obstructive pulmonary disease secondary to cigarette smoking, and cirrhosis, neuropathies, or cardiomyopathy secondary to alcohol dependence. In addition, opioid addicts have the same chronic diseases that are seen in the general population. Especially significant are diabetes and hypertension, which are among several chronic conditions that require treatment throughout all AOD treatment phases. Other conditions, such as cellulitis, are acute and require much shorter periods of treatment, or they resolve without intervention.

In some communities, more than 50 percent of injection drug users are HIV infected. TB is a growing problem among substance abusers, and almost half of the patients in some treatment programs have positive tuberculin skin tests.

At a minimum, the initial medical evaluation should determine the presence of physical dependence and inquire about a history of AIDS or HIV infection, cirrhosis, hepatitis, and TB. Women of childbearing age should be questioned about the possibility of pregnancy.

Psychiatric Conditions

Most psychiatric conditions found in the general population are also found among persons dependent on opioids. Compared with the general population, opioid-dependent persons are more likely to have other substance use disorders; depressive disorders; Post Traumatic Stress Disorder (PTSD); substance-induced psychotic, mood, and anxiety disorders; and antisocial personality disorder. Mood disorders (major depression and dysthymia), anxiety disorders, and antisocial personality disorder are the conditions most commonly encountered. This pattern of comorbidity has been reported in numerous studies ([O'Brien et al., 1984](#); [Rounsaville et al., 1982b](#)). Another TIP in this series, *Assessment and Treatment of Patients With Coexisting Mental Illness and Alcohol and Other Drug Abuse*, describes many commonly occurring mental disorders and provides guidelines for treating dually diagnosed patients.

Comorbid psychiatric disorders should not exclude a patient from admission to opioid substitution therapy, but identification of the presence of a disorder and a current diagnosis are critical to matching the patient to appropriate services for successful treatment. A preliminary

assessment should include a mental status examination and a drug history. The results of the initial examination can determine whether further assessment and additional services are needed. For example, if a patient reports a history of suicide attempts or presents vegetative signs of depression, including helplessness, hopelessness, and thoughts about suicide, then hospitalization for protection and containment or prescription of antidepressant medication may be indicated. Further, if a patient presents with manic symptoms, it should be determined whether the symptoms are substance induced or whether the etiology is an undiagnosed primary mood disorder. In either case, lack of attention to these presentations may result in the patient's receiving ineffective or inappropriate treatment, or even in the patient's doing harm to him- or herself or to others.

Polydrug use and psychiatric problems are both associated with negative treatment outcomes unless they are identified and treated. Most substances of abuse produce moderate to severe psychiatric symptoms, and in most patients there is a complex association between substance use and psychiatric status. Therefore, assessment is critical to determining whether such symptoms represent primary psychiatric disorders or substance-induced conditions, since the former do not dissipate with abstinence and require longer-term treatment. Program staff often focus on the condition that is most severe and threatening; however, it is usually important to simultaneously address the other disorder since each problem can exert a negative influence on the other.

Attention deficit-hyperactivity disorder (ADHD), although not as common as other psychiatric disorders, can be found in this population. In patients with this disorder, stimulants may have an adaptive effect, especially if taken consistently and in low doses. Use of cocaine by such patients may be an attempt to control symptoms of ADHD. Adult ADHD is difficult to diagnose. Patients with ADHD can usually be identified by taking a careful history, performing a mental status examination, and administering neuropsychological tests. Such tests are not typically carried out by treatment programs; rather, patients are referred for testing to outside clinical psychologists or psychiatrists.

If ADHD exists and is severe, treatment with stimulant drugs such as methylphenidate (Ritalin) or pemoline should be considered since treatment may improve the ADHD as well as address the cocaine or other stimulant use disorder. However, Ritalin use should be carefully monitored, since some patients will abuse the drug by injecting it, and medical complications can result from such long-term injection use.

Housing, Family, and Social Problems

Substance abuse and alcoholism are found in 30 to 40 percent of the homeless population; severe mental illness affects about 30 percent. Heroin, cocaine, and crack use are major causes of homelessness for 10 to 20 percent of the homeless population nationwide. The incidence of AIDS among the homeless is significantly higher than in the general population ([Wright, 1990](#)). Health conditions such as vascular disease, trauma, hypertension, poor dental health, gastrointestinal disorders, liver disease, neurological and seizure disorders, arthritis, tuberculosis, and syphilis are also more prevalent. In addition, homeless patients are usually undereducated and in need of vocational assessments and services ([Joseph, 1992](#)).

Many patients entering opioid substitution therapy programs are homeless. Addressing their needs at the time of admission is a high priority. If these needs are not addressed, such patients are unlikely to engage successfully in treatment. Patients living with other addicted individuals or in buildings or neighborhoods where the use of drugs is commonplace require special support services or help to secure more appropriate living arrangements. Programs should screen for these problems and must establish referral relationships with housing agencies or other programs that address the special needs of the homeless.

Many patients entering opioid substitution therapy programs are homeless. Addressing their needs for housing at the time of admission is a high priority. If these needs are not addressed, such patients are unlikely to engage successfully in treatment.

Family conflict secondary to drug abuse and to many other problems should be expected for all patients entering treatment. The preliminary assessment should include questions about family relationships and problems (including domestic violence); whenever possible, relatives and sexual partners should be included in the assessment process. Program staff must also be sensitive to special issues related to atypical family arrangements. For example, programs with significant numbers of single parents should consider establishing childcare programs onsite to facilitate treatment participation by the parents. Because family problems are so common, every opioid substitution therapy program should have at least one staff member skilled in family evaluation and family therapy.

Review of Treatment Options

Once the initial assessment has been completed in the areas indicated above, treatment options should be developed and reviewed with the patient. In most cases, these options include

- Opioid substitution therapy
- Therapeutic community
- Inpatient or outpatient detoxification programs
- Inpatient or outpatient psychiatric treatment
- Rehabilitative day hospital treatment
- Outpatient drug-free counseling programs, often with the use of naltrexone
- Acupuncture ([see Chapter 4](#)).

The interviewer should begin by familiarizing the patient with the range of treatment possibilities. The ensuing negotiations should focus on five questions:

- What is the most appropriate option?
- What is realistic?
- What is available?
- What does the patient want?
- What will the patient accept?

Responses to each of these questions will narrow the range of options. If, for example, a female candidate for treatment is pregnant, a program that offers comprehensive resources for pregnant and postpartum women should be recommended. Other factors that should be incorporated into decisionmaking include the patient's living arrangements, family and peer support systems, sexual orientation, and employment and legal history.

As stated earlier, treatment modalities may be combined. For some patients, residential treatment or day treatment and opioid substitution therapy may be appropriate if available. A patient addicted to opioids and alcohol, benzodiazepines, or cocaine may need inpatient detoxification from these substances in a facility that can initiate or maintain opioid substitution therapy prior to discharge to an opioid substitution therapy program. Some patients may elect to combine substitution therapy with acupuncture.

Selecting an Option

For many patients with chronic opioid dependence, the best options are admission to outpatient substitution therapy or entry into a therapeutic community. A small proportion of voluntary admissions will elect to use naltrexone; court-mandated patients tend to choose naltrexone more frequently than other patients ([Brahen et al., 1984](#); [Cornish et al., 1993](#)).

Despite 25 years of demonstrated success using methadone for the treatment of chronic opioid dependence, some treatment providers still question its efficacy. For example, services sometimes mandate withdrawal from methadone as a condition of admission. Some residential programs allow methadone-maintained patients to enter treatment on the condition that they become methadone free within 6 months. For many patients, this condition represents an unfair and unjust pressure that can sabotage long-term treatment outcomes.

When considering treatment options for this patient population, creativity is important. Although patients should be encouraged to detoxify when they are stable and motivated, it must be recognized that some patients will need to remain in substitution therapy for an extended period. Programs that require withdrawal from methadone should be avoided whenever possible; however, gaining access to programs that provide environmental support, or additional detoxification services with continued methadone treatment, is not always possible. Opioid substitution therapy programs can offer treatment alternatives for patients who need containment and methadone treatment when both are not available. For example, the program can develop a contract with the patient stipulating that the patient has the option of returning to the program after completing residential or inpatient treatment. This option may help the patient access the services needed without feeling abandoned by the methadone treatment program.

Final Determination of Eligibility for Opioid Substitution Therapy

The Medical Assessment

The purpose of the medical evaluation is to gain more information about impressions revealed by the initial assessment and to determine the existence of objective evidence of opioid dependence,

as reflected by signs and symptoms of opioid tolerance and withdrawal and other signs of chronic opioid use, such as needle marks.

When considering treatment options for this patient population, services that mandate detoxification as a condition of admission should be avoided. For example, some residential treatment programs allow methadone-maintained patients to enter treatment on the condition that they become methadone free within 6 months. For many patients, this condition represents an unfair and unjust pressure that can sabotage treatment response.

The Dimensional Admission Criteria for Acute Intoxication and/or Withdrawal that are contained in the *Massachusetts Criteria: Admission, Continuing Care, and Discharge*, developed by the Massachusetts Methadone Treatment Providers Association and the Massachusetts Department of Public Health, are recommended for guidance during the medical evaluation ([Massachusetts Department of Public Health, 1992](#)) (see Appendix B). These criteria, which pertain exclusively to methadone treatment, are based on the generic placement criteria defined in *Patient Placement Criteria for the Treatment of Psychoactive Substance Use Disorders* developed by the [American Society of Addiction Medicine \(1991\)](#).

As described in more detail in an earlier TIP *State Methadone Treatment Guidelines*, one key element is the physician's determination that the patient is "currently physiologically dependent on an opioid drug and became physiologically dependent at least 1 year before admission for comprehensive maintenance treatment." A 1-year history of addiction, the regulations note, means that an applicant was "physiologically addicted to a narcotic at a time at least 1 year before admission to a program and was addicted, continuously or episodically, for most of the year immediately before admission to a program," FDA, March 2, 1989; updated in 21 C.F.R. Part 291 § 291.505 at 129 (1993).

Criteria to determine the patient's current physiological dependence and history of addiction include but are not limited to vital signs, early physical signs of opioid withdrawal, a positive urine screen for opioids, presence of old or fresh needle marks, documented medical or AOD treatment history, patient and family reports, medical records, and so forth ([see Appendix B](#)).

Exceptions may be made for the following three groups of patients:

- Pregnant women with a documented history of opioid dependence, current use, or imminent relapse.
- Persons who have resided in a penal institution or chronic care facility for 1 month or longer and
 - Have been admitted to methadone treatment within 14 days prior to release or discharge or within 6 months of release or discharge without documented evidence of physiological dependence
 - Would have been eligible for admission before their incarceration or institutionalization
 - Are, in the clinician's judgment, about to relapse.

- Persons who have completed voluntary detoxification from methadone maintenance within the last 2 years and have relapsed or are at high risk of relapsing.

Another important element is the ability to provide or obtain a comprehensive medical history, medical evaluation, and laboratory tests. Laboratory tests must include routine blood work and a serological test for syphilis and hepatitis, a tuberculin skin test, and a test for determining recent use of drugs. The program must ensure that HIV counseling and testing are available to patients upon request. The physical examination must include an investigation of the organ systems, determination of vital signs, and an assessment of the patient's overall health status, FDA, March 2, 1989, and updated in 21 C.F.R. Part 291 § 291.505 at 132 (1993).

Clinical Decisionmaking

Although all patients admitted to opioid substitution therapy must fulfill the criteria set forth in Federal regulations, individual States and third-party payers such as managed care systems may also impose additional admission criteria. It is ultimately the responsibility of the program physician to decide whether to recommend an individual for admission to treatment; thus, clinical judgment is vital to initiating substitution therapy.

Certain patients are not good candidates for opioid substitution therapy, including

- Individuals who have abused opioids episodically but who are not dependent
- Individuals with acute opioid dependence (for less than 1 year) with no prior treatment history
- Chronic opioid-dependent individuals who do not want opioid substitution therapy
- Patients living in areas where opioid substitution therapy is unavailable or not easily accessible.

Inclusion, rather than exclusion, should be a guiding principle of clinical decisionmaking. Few psychiatric or medical diagnoses automatically rule out the possibility of admission. Cross-addiction, as noted above, should not eliminate a person from consideration for opioid substitution therapy; however, it might delay admission if the patient requires inpatient detoxification from alcohol, benzodiazepines, or other sedatives, or a period of stabilization to control cocaine use. An inclusionary admission policy generally requires greater resource availability and program flexibility. Many parenting women, for example, will be able to enter treatment only if day care is available for young children. Many persons with chronic psychiatric problems can be effectively treated in opioid substitution therapy programs if psychiatric consultation is available.

Admission to Substitution Therapy

Admission to treatment marks the beginning of a collaborative relationship between the patient and the clinical team. It may in some cases signal a crisis in the patient's life that, if appropriately managed, will become an opportunity for positive change. Initial impressions strongly influence the patient's motivation and future treatment course. While many agencies or clinics may eventually share responsibility for meeting the multiple needs of the patient, the treatment program holds primary responsibility for developing and monitoring the treatment plan and coordinating ancillary services.

Patients who are not good candidates for opioid substitution therapy include individuals who have abused opioids episodically but who are not dependent, have acute opioid dependence (for less than 1 year) with no prior treatment history, are chronically opioid dependent but do not want opioid substitution therapy, or live where opioid substitution therapy is unavailable or not easily accessible.

The therapeutic relationship should begin with a discussion of the preliminary or initial treatment plan, which is based on the findings of the screening assessment and a review of program rules. The preliminary treatment plan should set forth short- and long-term goals. Methods of measuring patient progress also should be explained. The program rules should cover policies pertaining to patient rights and protection of confidentiality. Protocols governing disciplinary proceedings should be explained, and circumstances under which a patient may be placed on probationary status or involuntarily discharged from treatment should be defined. The counselor must be confident that the patient understands the goals and rationale for the treatment plan and program rules. A written statement of program rules and treatment expectations should be given to every patient.

Before being formally accepted into the treatment program, the patient should sign the "Consent to Treatment With An Approved Narcotic Drug" (Form FDA 2635 [7/93]), the program rules, and the preliminary treatment plan.

Matching Patient Needs for An Array of Services: The Comprehensive Assessment

As described further in [Chapter 3](#), the first 4 to 6 weeks in opioid substitution therapy are a critical period for patient and counselor. This is an excellent opportunity to observe the patient and to develop a comprehensive treatment plan. Original treatment goals may change after the patient can be observed when he or she is no longer intoxicated or experiencing withdrawal. Although assessment is ongoing throughout the course of treatment, it is especially important during the initial weeks.

Among the most important decisions made during this period is the selection of an appropriate methadone dosage, which is described more fully in [Chapter 4](#) and in a previous TIP in this series, *State Methadone Treatment Guidelines*. Adequate dosages have been shown to be a primary determinant of retention in treatment. The methadone dosage, like that of all prescribed drugs, should be individualized and based primarily on the patient's response to the medication. Although the reliability of measuring blood levels of methadone as a means of determining adequate dosage is controversial, such tests may be helpful in identifying patients who metabolize methadone rapidly (a peak level within normal limits, 400 nanogram/mililiter [ng/ml], and a trough level of less than 150 ng/ml). Methadone's effectiveness is dose dependent, and higher doses generally are more effective than lower doses.

After the patient is formally admitted to the opioid substitution therapy program, a comprehensive assessment should be conducted. Specific instruments should be used to collect quantitative data about the patient's problems and range of needs. A primary evaluation instrument and, in some cases, selected secondary instruments, are used. The assessment, which may take place over several sessions, should also include a detailed interview about the patient's treatment history, as well as his or her expectations about treatment and motivation to participate. The information gathered during the comprehensive assessment process can be used to refine the preliminary treatment plan, to set more individualized treatment goals, and to establish a baseline of functioning that can be used to measure progress. Assessment is essential to appropriately match patients to type and level of care.

The methadone dosage, like that of all prescribed drugs, should be individualized and based primarily on the patient's response to the medication. Although the reliability of measuring blood levels of methadone as a means of determining adequate dosage is controversial, such tests may be helpful in identifying patients who metabolize methadone rapidly.

The Primary Assessment Instrument

Patient status should be assessed with a comprehensive and reliable instrument. The National Institute on Drug Abuse has published a useful resource book -- the *Diagnostic Source Book on Drug Abuse Research and Treatment* -- to assist substance abuse treatment personnel in choosing appropriate instruments. The book describes and evaluates a variety of tools for assessing patients' needs in many areas.

The Addiction Severity Index (ASI) (McLellan et al., [1980](#); [1990](#)) or the Intake Form developed under the Drug Abuse Treatment for AIDS-Risk Reduction (DATAR) Project at Texas Christian University ([Rounsaville et al., 1993](#); [Simpson, 1992](#)) are among the comprehensive instruments used¹.

A valid assessment tool must contain quantifiable indicators used to measure progress in specific domains and to track the patient through treatment. The instrument also should be useful to program managers who wish to assess program effectiveness.

The ASI assesses seven domains: drug use, alcohol use, medical needs, psychiatric needs, family and social support systems, legal needs, and vocational needs. Patients are asked specific questions within each domain, and scores indicating the need for treatment or intervention are then formulated. Persons administering the ASI must receive training in its use; refresher training and reevaluation must be conducted periodically.

Principal areas included in the DATAR Intake Form are sociodemographic background, family background, peer relations, criminal history, health and psychological status, drug history, and

acquired immunodeficiency syndrome (AIDS) risk. The form provides a comprehensive assessment of these areas but does not include standardized scoring procedures or clinical norms.

The area of AIDS risk, which is not separately covered in the ASI, is an essential part of the assessment. Questions about needle use and sexual practices that increase the risk of HIV infection, as well as questions about domestic violence and sexual abuse history, must be asked of all candidates for opioid substitution therapy.

The panel recommends that whatever assessment tools are used cover at least the following areas

- Drug use (injection and noninjection)
- Alcohol use
- Medical history and status
- HIV serostatus or risk
- Psychiatric history and mental status
- Family relations and supports
- History of domestic violence and sexual abuse
- Community and peer relations and supports
- Housing status
- Criminal history and legal status
- Educational history
- Employment history and status
- Military or other service history.

An assessment of the patient's treatment history, a cultural assessment, and a determination of the patient's expectations and motivation are also key elements of the biopsychosocial assessment and are described in this chapter.

When selecting an assessment tool, program staff should be reminded of the difficulty in developing a reliable and comprehensive assessment instrument. Existing instruments should be used or tailored, when necessary, to a specific population or program.

Secondary Assessment Instruments

The initial assessment often reveals the need for a more focused evaluation in one or more domains. Clinical staff should be familiar with diagnostic instruments available in each of the assessment areas. They may then select the instrument(s) that best meet the patient's needs. The *Diagnostic Source Book on Drug Abuse Research and Treatment* ([Rounsaville et al., 1993](#)) also contains descriptions of recommended secondary instruments or measures to use in six areas:

1. Demographic characteristics, employment history, and legal history
2. Alcohol and drug use history
3. Medical history and medical consequences of AOD abuse
4. Psychiatric diagnosis
5. Family functioning
6. Social adjustment and social supports.

Need for Quantitative Data

Assessment data traditionally have been recorded in narrative form. While use of clinical treatment notes will undoubtedly continue, program staff should ensure that data also are recorded in quantitative form. Collecting data on specific dimensions can provide valuable information about a program's patient population and can assist clinicians in matching patient needs to program services. For example, collecting data about patient health status on admission and at specific intervals throughout treatment can provide valuable information to the program about the health status of the patients served and their progress or changing needs throughout treatment.

Quantitative data can assist clinicians in program planning, advocating for funds, and developing relationships with affiliated agencies. Monitoring program operations and treatment outcomes is increasingly important in an era of scarce resources and managed care. (The TIP *Developing State Outcomes Monitoring Systems for Alcohol and Other Drug Abuse Treatment* provides guidelines for gathering useful data.)

Evaluation of Earlier Treatment Experiences

The patient's treatment history is a useful indicator of future treatment needs. For this reason, the clinician should solicit as much information as possible concerning this subject. To supplement the patient's self-reports, summaries and records should be requested from programs in which the patient previously has been enrolled. This information will give the clinical team an understanding of approaches that have and have not worked well for the patient.

Of particular importance is information about psychiatric symptomatology during periods of abstinence, which may help the clinician differentiate symptoms induced by drugs from primary psychopathology. An exploration of past periods of abstinence also may reveal important clues to effective management approaches. An awareness of the patient's response to mandatory abstinence (for example, during periods of incarceration) may provide valuable insight into character structure and coping skills.

Physical and Sexual Abuse

Some information important in treatment planning is not easily accessible using a specific assessment tool. For example, some patients may have significant histories of physical and sexual abuse, which they may deny during the interview process or in responding to a question on an assessment tool. Gathering this kind of information is a delicate process, and extreme care must be taken when pursuing this line of questioning. For example, a battered woman may deny being abused even when questioned about a visible injury. The patient may not be ready to address the problem, or may be concerned that revealing this information will put her at further risk.

Creating a safe atmosphere is important, and respecting the patient's hesitancy to reveal information is critical. An important initial step is for the clinician to let the patient know that he or she is aware that a problem might exist and that the clinician is available to discuss it. As the

therapeutic relationship develops, the patient may be more willing to reveal and discuss abuse issues. Making resources such as shelters and support groups available to the patient is also helpful.

Cultural Assessment

A key part of a biopsychosocial assessment is a cultural assessment, that looks at cultural values and assumptions of various populations. For example, some Native Americans, Asian Americans, and new immigrants have strong traditional and religious ties. Other members of these groups may have been assimilated into the "mainstream" American culture. Knowledge of how different cultural groups define a family unit or work through problems is important to providing services to multicultural and ethnic groups. For example, a desire to confine knowledge about problems just to family members may be part of a patient's culture and may result in resistance to counseling or family therapy, even when obvious personal or family problems are contributing to AOD use. Some patients who will not confide in treatment providers may, however, seek counseling from someone at their church. Cultural and ethnic considerations should inform the design of programs and individual patient treatment plans.

Gathering information about domestic violence and sexual abuse is a delicate process, and extreme care must be taken when pursuing this line of questioning. Creating a safe atmosphere is important, and respecting the patient's hesitancy to reveal information is critical.

Limited knowledge of the cultural context of substance use disorders has resulted in treatment approaches that sometimes seem irrelevant or conflictive to specific populations. It is important to understand that how a minority cultural group views illness and treatment may have an influence on group members' entering treatment and using services. For example, an awareness that one is addicted may be unacceptable to some Asian patients. Asian Americans may enter treatment late because personal loss of control runs against the norm of many Asian cultures. Many ethnic healing traditions are focused on brief, magical cures with consultation from many healers. Such a belief system may make it difficult for some individuals to accept the long-term focus of opioid substitution therapy.

A Hispanic-American patient may view compulsory urine testing as indicative of the program's mistrust of the patient's word; testing may offend his or her sense of dignity, a highly relevant and strongly defended principle among many members of this ethnic group. The prospect of long-term substitution is seen as a modern form of "slavery" by some African Americans. Some Puerto Rican patients who have been forced to assimilate into the Anglo culture suffer from an identity crisis. They often feel that their culture is devalued, that they have been fragmented from their extended family networks and polarized between generations. These issues, along with language barriers, should be considered in the assessment and treatment planning process ([Ruiz et al.](#)).

A shared staff-patient cultural identity is more attractive to some patients entering treatment. To the extent possible, staffing should reflect the population being served by the program. Use of bilingual educational materials and display of materials in the program waiting room can be helpful in making patients feel comfortable when English is not the primary language.

Determination of Patient Expectations and Motivation

Because effective matching must take into account patient preferences, the clinician should carefully explore the patient's wishes and expectations from opioid substitution therapy. During this process, the patient should be treated with dignity and respect. Clinician-patient interchanges should take the form of negotiations between two parties working toward a mutual goal.

Limited knowledge of the cultural context of substance use disorders has resulted in treatment approaches that seem irrelevant or conflictive to specific populations. It is important to understand that how a minority cultural group views illness and treatment may have an impact on group members' entering treatment and using services.

The role of patient motivation, readiness, and suitability for treatment cannot be overemphasized. Poor motivation has been found to be a predictor of early dropout from AOD abuse treatment ([De Leon and Jainchill, 1986](#); [Simpson and Joe, 1993](#)). Clinicians should be able to assess the patient's motivation and readiness for change ([De Leon and Jainchill, 1986](#)); mastery of the techniques of motivational interviewing is an invaluable clinical skill ([Miller and Rollnick, 1991](#)).

The Process of Change

The clinical team can benefit from an understanding of the stages of change and their impact on patient progress. Building on the work of [Cashdan \(1973\)](#), and [Egan \(1975\)](#), and [Horn and Waingrow \(1966\)](#), Prochaska and colleagues ([1982](#); [1986](#); [1992](#)) formulated a model that explained how people change. Applying their model to the treatment of addictive behavior, these authors proposed five stages of change:

- Precontemplation
- Contemplation
- Preparation
- Action
- Maintenance.

Change begins as a cognitive process and moves incrementally toward the behavioral domain. Movement through these changes is similar to the process of recovery; a period of progress may be followed by a retrenchment. Just as a majority of patients will relapse one or more times

before recovery from AOD dependence, most patients will return to a previous stage before moving definitively to the next stage.

A treatment intervention may be appropriate or inappropriate, depending on the patient's position on the change continuum. Interventions that are appropriate to the patient's current stage of change enhance the possibility of positive treatment outcomes; in other words, one must do the right thing at the right time. Patients in the contemplative stage of change, for example, are usually ambivalent about stopping AOD use; consequently, a nondirective, client-centered technique designed to help the patient resolve such ambivalence may be helpful. A patient in the active stage of change, by contrast, is generally amenable to a directive intervention that may include recommendations for specific therapeutic activities.

Finally, assessment of motivation requires that the clinician know when to encourage the patient and when to realize that limits have been reached. While movement toward recovery remains the foremost goal, the clinician also must realize that progress must come at a pace with which the patient is comfortable.

Patient Matching: Two Examples

Once needs have been assessed and internal and referral resources identified, the second step in the patient matching process -- identifying needed health, mental health, and ancillary services -- can begin. The following examples, one using the Addiction Severity Index for assessment of psychological status and one using the Massachusetts Methadone Treatment Criteria ([Appendix B](#)), illustrate how specific tools can assist in problem identification, treatment planning, and the matching process.

Example 1: Mr. G

Mr. G, who is 38 years old, is applying for admission to a methadone maintenance program. He reports that he has experienced hopelessness and loss of interest in everything. He spends most of the day in bed except for buying and using heroin to prevent withdrawal. He recently lost his job because of poor attendance. He reports that since his early teens he has experienced pervasive anxiety, periods of depression, and trouble concentrating. These conditions predate his drug use. In fact, he believes that drugs have helped him feel less anxious and more focused so he can work. However, he reports that drugs no longer have this effect. He has made two serious suicide attempts (a deliberate overdose and crashing his car into a tree). He has transient thoughts of suicide now but no specific plan. He has used antidepressants in the past, but had to discontinue use because he couldn't afford the medication.

The ASI (or a comparable assessment tool) is administered upon admission to assess, among other indicators, Mr. G's psychological status. He scores higher than 5 on the psychiatric scale. Identifying specific indicators for depression is an important part of this patient's initial assessment. The counselor could further investigate Mr. G's psychiatric complaints and should refer the patient for a more comprehensive psychiatric evaluation. If the evaluation reveals a specific condition, such as major depression, Mr. G should be referred to a psychiatrist, who can determine whether antidepressant medication, psychotherapy, or a combination of these

treatments is appropriate. Identification and treatment of the patient's comorbid condition could be a critical factor in retaining Mr. G in the opioid substitution therapy program.

Assessment of motivation requires that the clinician know when to encourage the patient and when to realize that limits have been reached. While movement toward recovery remains the foremost goal, the clinician also must realize that progress must come at a pace with which the patient is comfortable.

Example 2: Ms. J

Ms. J is a 45-year-old divorced mother of two (a 10-year-old son and a 5-year-old daughter), who has been in methadone maintenance treatment for 10 months. Her children are currently living with a relative. Ms. J is receiving 85 mg of methadone and has stopped using heroin. In the last 2 months, her urine test results have been positive for cocaine, and she reports that her current partner deals and uses cocaine. Upon admission, her liver function tests are elevated and she tests positive for hepatitis B and C. Although she had not shared needles in the last 18 months, she has done so with her partner a few times in recent weeks. She has not been HIV tested because she is afraid to learn her status.

Ms. J attends counseling on a regular basis but is hesitant to attend community support groups such as Narcotics Anonymous. She recognizes the severity of her opioid addiction and minimizes her cocaine use. She has learned to recognize some of her relapse triggers, but she does not have sufficient coping skills to interrupt cravings or impulsive use at this time.

According to the Massachusetts Methadone Treatment Criteria, Ms. J demonstrates the need for continued care in all of the outlined dimensions for methadone maintenance. For example, she needs ongoing medical monitoring for her hepatitis and medical problems, while demonstrating her ability to make use of the treatment environment. She has biomedical complications, specifically for her liver problems and hepatitis, and is at risk of HIV infection. Her episodic use of cocaine is also a problem. Once her biomedical needs have been identified, Ms. J should be referred to a primary care physician for blood work and continued medical followup. A counselor should attempt to explore her resistance to HIV testing and describe pre- and posttest counseling that may help motivate, support, and provide further education about HIV risk factors.

Indicators of emotional-behavioral conditions provide evidence that Ms. J has responded to treatment and has made some life-change progress, but she continues to manifest risk behaviors such as needle sharing. She recognizes the severity of her addiction to heroin but demonstrates minimal understanding of her cocaine use and its relationship to her risk of relapse to heroin use. Ms. J requires continued treatment to begin to address her AOD use. She recognizes some relapse triggers for heroin use but has not developed sufficient skills to resist AOD use. In addition, Ms. J's living environment is not conducive to recovery, and she has not developed the socialization skills to establish a supportive network.

Groups focusing on cocaine use, identifying risk factors, and exploring ambivalence to change might be helpful. Further discussion and understanding of her relationships with her partner and her children, of her home environment, and of her goals for change may help identify the specific services that can assist her in this effort.

Identifying the issues for Ms. J according to the dimensions in the Massachusetts criteria can be helpful in identifying specific areas for treatment planning and recognizing and documenting progress in treatment. Uniform documentation, whether using the ASI, the Massachusetts criteria, or other assessment tools, can help quantify progress and identify specific needs for further assessment and continued treatment.

Assessing Patient Progress

Patient progress is monitored against baseline functioning as identified during the initial assessment. Progress should be assessed and confirmed by subsequent medical and psychosocial evaluations from the perspectives of the patient and the program. Patient assessment is discussed here; program assessment is covered in [Chapter 5](#).

Clearly Defining Initial Treatment Goals

Patient progress can be assessed only after treatment goals have been clearly articulated, shared with the patient, and jointly accepted. The treatment plan should balance program requirements and patient needs. It should define short- and long-term goals and set forth information on the level, duration, and frequency of counseling and other services. Pertinent information related to treatment goals must be clearly reflected in the assessment forms.

Patient progress cannot be assessed effectively if treatment goals have not been articulated clearly, shared with the patient, and jointly accepted.

Assessing Patient Progress and Services Received

Selection of the Ongoing Assessment Instrument

A simple, well-structured instrument that captures the full range of patient variables is essential to ongoing assessment of patient progress. The assessment instrument, which should be integrated with the program's management information system, must be not only scientifically accurate but also user friendly. Staff must feel comfortable administering it, and patients must not feel that it is intrusive or time consuming.

For periodic assessment of patient progress, programs may use the same instrument that is used for initial assessment. Ideally, whatever tool is used for ongoing assessment should gather data that can be compared to the data gathered at baseline. Data collected by instruments used to

assess patient progress, like data collected during the initial assessment, should be quantifiable. Maintaining information in this format makes it easier to establish objective signs of progress and to evaluate program effectiveness. Several assessment instruments are available for use in opioid substitution therapy programs. They vary considerably in length and scope. As mentioned previously, the National Institute on Drug Abuse has also published a helpful document, *Diagnostic Source Book on Drug Abuse Research and Treatment*, which describes a variety of assessment instruments.

To adequately track services being delivered and patient progress toward treatment goals, the chosen assessment instrument(s) should cover a minimum of three of the areas described below.

Ongoing measures of use of heroin, opioids, alcohol, and other drugs. These include self-reports, urine toxicology screens, Breathalyzer reports, or other tests. Alcohol problems are common among patients with opioid addiction and sometimes precipitate or indicate relapse to opioid use. Programs are encouraged to use Breathalyzer tests to supplement urinalysis. Such tests provide immediate feedback on blood alcohol levels, making it possible to respond promptly to indications of alcohol use. For example, in some programs it is a policy that a patient's blood alcohol content must be zero before a methadone dose can be given. Withholding of doses in such cases is not punitive; rather, it is part of treatment and provides an important clinical message to patients.

Service delivery and compliance. This can be measured in terms of session attendance, tracking missed appointments, and other signs of patient engagement.

Psychosocial and behavioral functioning. Functioning is generally monitored by the counselor during patient interviews.

The patient's role in assessing treatment progress. Instruments for collecting patient feedback are necessary components of the assessment battery. The patient's input concerning his or her treatment course must be sought regularly; 3-month intervals are generally appropriate. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that treatment plans be made every 90 days. Federal regulations require 90-day treatment reviews during the first year of treatment, and 6-month reviews thereafter. Instruments that document the patient's view of his or her progress must be included in the treatment plan.

Program forms should be designed so that patients are not required to comment on individual staff members; many patients may be reluctant to provide information that is too personalized. Rather than asking the patient how he or she feels about a counselor, the question should be posed in terms of the counseling.

Interpreting Patient Progress

Any significant change in patient status revealed by the assessment, whether positive or negative, should be viewed as an opportunity to reassess the treatment plan and determine whether the mix and intensity of services are appropriate. As described in [Chapter 3](#), services may need to be more intensive during times of crisis and decreased when sufficient progress is made. For

example, increased counseling services provided to a patient after the death of a partner, family member, or friend may provide the support needed to prevent relapse. Requiring attendance at a specialized group for those struggling with cocaine use can help a patient attain the skills and support to control or stop use. Responding to a positive urinalysis by developing a more responsive treatment plan can work to ensure good treatment outcomes. Providing positive feedback, readjusting counseling services, and increasing privileges can demonstrate to the patient that progress has been made and less monitoring is needed. Programs should be ready to increase services in response to acute crises, even for patients who have been stable for a long time.

Conclusions and Recommendations

Opioid substitution therapy is an effective means of managing opioid addiction. Although not all patients completely stop drug use, the great majority substantially reduce use and show progress in one or more other areas as well. Opioid substitution therapy is best provided within a treatment program offering a range of services and in an atmosphere of structure and support. Adequate dosage, delivery of ancillary services as needed, and retention in treatment are the key determinants of positive outcomes for persons who are addicted to opioids. Matching patients to treatment services increases the probability of their retention in treatment and of a positive outcome, and therefore has an essential role in opioid substitution therapy.

Any significant change in patient status revealed by the assessment, whether positive or negative, should be viewed as an opportunity to reassess the treatment plan and to determine whether the mix and intensity of services are appropriate.

Several recommendations have been made in this chapter and are summarized below:

1. The preliminary assessment to determine eligibility for opioid substitution therapy should include a minimum of five areas:
 - Determining the need for emergency care
 - Diagnosing the presence and severity of opioid dependence
 - Determining the extent of AOD use
 - Screening for medical and psychiatric comorbid conditions
 - Evaluating the individual's living situation, family and social issues, and legal problems.
2. At a minimum, the initial medical evaluation should determine the presence of physical dependence on opioids and inquire about a history of AIDS or HIV infection, cirrhosis, hepatitis, and TB. Women of childbearing age should be questioned about the possibility of pregnancy.
3. Inclusion, rather than exclusion, should be a guiding principle of clinical decisionmaking about admission to substitution therapy. Few psychiatric or medical diagnoses automatically rule out the possibility of admission.
4. After formal admission to opioid substitution therapy, a comprehensive assessment should examine the following areas:
 - Drug use (injection and noninjection)

- Alcohol use
 - Medical history and status
 - HIV serostatus or risk
 - Psychiatric history and status
 - Family relations and supports
 - History of physical, emotional, and sexual abuse
 - Community and peer relations and supports
 - Housing status
 - Legal status
 - Educational history
 - Employment history and status
 - Military and service history
5. An assessment of the patient's treatment history, a cultural assessment, and a determination of the patient's expectations and motivation are key elements of the biopsychosocial assessment.
 6. The assessment instrument, which should be integrated with the program's management information system, must be not only scientifically accurate but also user friendly. Staff must feel comfortable administering it, and patients must not feel that it is intrusive or time consuming.
 7. Developing a reliable and comprehensive assessment instrument is difficult. Existing instruments should be used or tailored, when necessary, to a specific population or program.
 8. Clinical staff should be familiar with secondary assessment instruments that focus on particular life areas.
 9. Assessment data should be recorded in quantitative form.
 10. To adequately track services being delivered and patient progress toward treatment goals, the ongoing assessment instrument(s) should cover a minimum of three areas:
 - Continued use of heroin, opioids, alcohol, and other drugs
 - Service delivery and compliance
 - Psychosocial and behavioral functioning.
 11. The patient's wishes and expectations of opioid substitution therapy should be carefully explored. During this process, the patient should be treated with dignity and respect.
 12. The opioid substitution therapy program should have primary responsibility for developing and monitoring the treatment plan and coordinating ancillary services.
 13. The methadone dosage should be individualized and based primarily on the patient's response to the medication.
 14. Any significant change in patient status revealed by ongoing assessment should be viewed as an opportunity to reassess the treatment plan and to determine whether the mix and intensity of services are appropriate.
 15. Providing opioid substitution therapy in a variety of treatment settings is necessary to meet patient needs. For example, residential and inpatient detoxification programs should allow the patient to continue methadone maintenance, if clinically indicated.
 16. The goal of voluntary withdrawal from methadone should be for the patient to become drug free. For example, a patient who is progressively resuming illicit drug use should be strongly discouraged from completing the detoxification process.
 17. Because psychiatric and family problems are so common, every opioid substitution therapy program should have at least one staff member skilled in psychiatric assessment and treatment and in family evaluation and family therapy.

Endnote

1. The *DATAR Forms Manual* ([Simpson, 1992](#)) includes copies of several useful instruments. The 13-page clinical version of the 5th edition of the Addiction Severity Index is reprinted in TIP number 7 in this series, *Screening and Assessment for Alcohol and Other Drug Abuse Among Adults in the Criminal Justice System*. The 28-page DATAR Intake Form is reprinted in full in Appendix C of the *Diagnostic Source Book on Drug Abuse Research and Treatment*, published by the National Institute on Drug Abuse.

Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series

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Chapter 3 -- Phases of Treatment

The concept of treatment phases can be useful in attempting to match patients and services. When treatment is conceptualized as occurring in phases, a patient can be regarded as engaging in a series of successive interventions within a single program, with each intervention building on the other and leading to one or more well-defined goals.

The concept of treatment phasing is by no means new to the field of alcohol and other drug (AOD) abuse treatment (Institute of Medicine, [1990a](#); [1990b](#)); however, this approach has not been widely used in methadone programs ([Kreek, 1991](#)). Nevertheless, many methadone programs operate at least partially according to an informal phased model of treatment, and others often recognize the need to utilize phases in developing treatment plans. The value of having treatment phases within methadone programs has been recognized by [Hoffman and Moolchan \(1994\)](#), who have described a phased and highly structured treatment model. This chapter builds on and extends that model as one important aspect of an overall strategy for matching patients to treatment.

In this chapter, each phase of a six-phase treatment model is described. Key issues typically arising in each phase are discussed, along with indicators of patients' progress through each phase and strategies to facilitate their progress. The model is not linear; patients may encounter setbacks requiring return to an earlier treatment phase. Thus, indicators of lack of progress and strategies for addressing setbacks are discussed. A separate section addresses transitions between phases, discharge, and readmission. Two clinical issues -- hospitalization of patients and decisionmaking about take-home medications -- are also discussed.

Scope of Treatment Phases

As shown in [Exhibit 3-1](#), treatment begins with the acute phase and progresses through the rehabilitation and supportive care phases. The model then branches out into three separate tracks according to the patient's progress. These tracks involve different types and intensities of treatment services that correspond to the patient's level of functioning. Patients who have achieved a high degree of stability but who continue to need methadone to maintain this level of stability enter the medical maintenance phase. Some patients may remain in this phase indefinitely. Others may be considered for methadone detoxification (medically supervised withdrawal), which is undertaken by reducing the dose over a period of weeks or months (tapering) under close supervision ([Exhibit 3-1](#)). Patients who complete tapering from methadone often enter a period of readjustment, and additional counseling may be needed to reinforce

coping and relapse prevention skills. Finally, an aftercare phase in which patients maintain periodic contact with the program is often desirable.

The phased model is based on the assumption that although most patients will need long-term or lifetime methadone treatment, the type and intensity of services will vary throughout the course of treatment. This assumption is based on studies showing that most patients move between periods of remission and relapse to heroin use and that relapse is common, especially after they leave methadone treatment ([Ball and Ross, 1991](#); [Condelli and Duntzman, 1993](#); [Dole and Joseph, 1978](#); [Hubbard et al., 1989](#); [Simpson et al., 1979](#)).

Patients do not always move through all phases, and some move back and forth between phases at different times. Many patients who enter the *Phases of Treatment* rehabilitation phase relapse to uncontrolled use and reenter the acute phase. Such returns should be perceived not as a failure of either the program or the patient, but rather as a reflection of the addiction problem. For some, this pattern of stabilization and rehabilitation continues without progress to the medical maintenance phase. Some patients who have completed medically supervised withdrawal from ethadone may have to resume maintenance and supportive care.

To be most effective, phases of treatment should be established not as a fixed series of steps that are assigned specific timeframes, but rather as a dynamic continuum that allows each patient to progress according to his or her individual needs. Patients move through a particular phase gradually or rapidly, depending on a variety of biopsychosocial factors that are discussed in this and other chapters. Treatment outcomes should be evaluated not solely in terms of how many phases the patient has moved through, but rather by the degree to which the patient's needs, goals, and expectations have been met by the treatment program.

Although distinct treatment phases can be identified, it is important to emphasize that the services in any phase must also be appropriate not only to that phase but also to individual characteristics of the patient. These needs vary according to many factors, including age, sex, culture and ethnicity, education, and socioeconomic level. As described in [Chapter 2](#), assessment of a patient's readiness for a particular phase, as well as assessment of his or her individual needs, should also occur on an ongoing basis ([Simpson and Joe, 1993](#)).

Finally, it should be noted that for many patients attendance at self-help groups such as Alcoholics Anonymous and Narcotics Anonymous, provides an important source of support and structure during all phases of treatment. Opioid substitution therapy programs should establish ties to local community groups and should encourage patients to attend.

Acute Phase

The acute phase of treatment generally comprises the first days, weeks, or months of methadone maintenance. During this time, the patient is usually struggling to reduce illicit drug use and begins work to reduce the intensity of the psychiatric, medical, social, legal, family, and other problems that are associated with dependence. The most immediate aim during this phase is to achieve a methadone dosage level that suppresses withdrawal symptoms for 24 to 36 hours, does not produce sedation, and markedly reduces heroin use. A high intensity of services is typically

needed during the acute phase of treatment, especially for patients with serious psychiatric, social, or medical problems.

In the following sections, important clinical issues to be addressed during the acute phase of treatment are discussed, strategies for addressing them are offered, and indicators for transition to the next phase are described. [Exhibit 3-2](#) summarizes these discussions.

Alcohol and Illicit Drug Use

One of the major goals of the acute phase is to eliminate opioid use as quickly as possible. This process involves

- Initially prescribing a methadone dose that will minimize the chances of sedation and other undesirable side effects
- Assessing the safety and adequacy of the dose
- Rapidly but safely increasing the dose to suppress acute withdrawal symptoms and discourage the patient from supplementing the methadone dosage with continued use of heroin.

As part of the stabilization process, it is critical for care providers to know what other drugs are being used. Most patients admitted to methadone programs have been using a variety of other substances, particularly cocaine and alcohol ([Hubbard et al., 1989](#)). Setting limits on other forms of illicit drug use and alcohol abuse is also a major goal of this phase. Urine screening should be conducted at least once a week. A recent study estimates that up to 75 percent of patients in methadone maintenance programs abuse cocaine ([Avants et al., 1994](#)). As described in [Chapter 4](#), group and individual counseling for cocaine abusers is an important treatment element.

Many patients continue heavy alcohol use after they are admitted to methadone programs ([Fairbank et al., 1993](#)). In fact, many patients, as well as many alcohol users, do not consider alcohol to be a drug. Continued heavy use is often a serious problem for methadone patients, and it will markedly impair progress in treatment. Although it may not be realistic to totally eliminate alcohol use by all methadone patients, its consumption should be strongly discouraged, especially since it often serves as a trigger for moving on to the use of cocaine and other illicit substances. Many programs use Breathalyzers to detect alcohol use and do not dispense methadone to intoxicated patients.

To be most effective, phases of treatment should be established not as a fixed series of steps that are assigned specific timeframes, but rather as a dynamic continuum that allows each patient to progress according to his or her individual needs.

Treatment staff should have frequent interaction with patients and should encourage ongoing dialogue concerning their symptoms. The counselor should make the patient feel comfortable in sharing information about all types of drug use and should not take a punitive approach if drugs

other than opioids are used. Such interaction allows for rapid adjustments in dosage and for other interventions as indicated. Extended clinic hours increase the availability of treatment providers, especially if they are needed on an emergency basis during the first few weeks of this phase.

Frequent contact with staff should facilitate the rapid elimination of opioid and other drug use. Extra sessions of individual or group counseling during this period can provide an added measure of support. Intensified treatment within the substitution therapy program is an important response to continued use of illicit drugs and alcohol abuse. Although methadone directly affects only opioid use, reductions in nonopioid use typically occur in the context of good therapy and counseling during methadone maintenance.

If opioid use continues or alcohol and other drug use poses a threat to the patient's progress and safety, a referral to inpatient treatment for a short time may be necessary. For some patients, methadone treatment is not the most appropriate modality, and referral to another therapy may be indicated. In other cases, the patient may respond to a program in which detoxification from other substances is completed while methadone maintenance is continued.

Criteria for transition from the acute phase into the next phase of treatment are

- The amelioration of signs of withdrawal
- Reduction in drug craving
- Demonstrable reduction in opioid and nonopioid drug use.

Some signs that the acute phase has ended are

- A subjective feeling that the methadone is stabilizing or "holding"
- An increased sense of well-being
- Changes in bowel function (decrease in or resolution of diarrhea or possible constipation)
- At least a few opioid-free urine tests.

Signs that a change in methadone dosage is needed include

- Continued opioid or other drug use to relieve subtle withdrawal symptoms
- Subjective complaints that the dose is not stabilizing or "holding" in the absence of signs and symptoms of sedation
- Continued illicit activities that reflect drug-seeking behavior.

The signs and symptoms that a dosage of methadone is too high include

- Drowsiness, nodding
 - Pinpoint pupils
 - Slowed speech
 - Respiratory depression and decreased vital signs
 - Euphoria
 - Flushing of skin.
-

Intensified treatment within the substitution therapy program is an important response to continued use of illicit drugs and alcohol abuse.

Psychiatric Problems

Acute symptoms of depression and anxiety are common among persons applying for treatment of substance use disorders. These symptoms are often markedly reduced or disappear after methadone stabilization, but sometimes they represent independent disorders that persist and need more specialized treatment. Post Traumatic Stress Disorder (PTSD), anxiety disorders, schizophrenia, bipolar disorder, antisocial personality disorder, and the entire range of psychiatric disorders that are seen in non-substance-abusing populations are seen among persons with opioid dependence. It is extremely difficult to diagnose independent psychiatric disorders during the early part of the acute phase of treatment, and a definitive diagnosis must often wait until the patient is stabilized.

When psychiatric disorders are present, there is usually increased difficulty in treating the substance use disorder. When the psychiatric disorder is treated with pharmacotherapy, psychotherapy, or a combination of these approaches, the substance use disorder is more likely to improve than when the psychiatric disorder is not treated ([Woody et al., 1984](#)).

Identification of persistent, independent psychiatric disorders that need ongoing therapy should be a focus during the acute phase so that the appropriate matching strategies can be formulated and implemented. Acute, substance-induced psychiatric disorders that do not need ongoing treatment should also be identified. Although these disorders usually resolve when the substance use disorder is under control, they can be very disruptive at the start of methadone maintenance, and patients may also need focused, short-term pharmacotherapy or psychotherapy. Since their course usually follows that of the substance use disorder, they typically do not require ongoing psychiatric treatment.

Medical Problems

The acute phase of treatment is often characterized by catastrophic medical problems requiring the use of significant and costly resources. These medical conditions must be stabilized before effective treatment can begin. Long-standing medical problems that may have been neglected during periods of drug use and prior to treatment entry must be addressed immediately. Such problems may include tuberculosis (TB), cellulitis, human immunodeficiency virus (HIV) infection, renal disease, diabetes, sickle cell trait or anemia, or cardiopulmonary diseases. Skin or organ abscesses secondary to repeated needle use or infection may require skin grafting, surgical correction, or aggressive pharmacotherapy. Any of these conditions may require hospitalization and incur substantial medical costs in a population that is typically lacking in financial resources.

As in the case of psychiatric problems, stabilization of acute medical conditions and the institution of ongoing care for chronic conditions are mandatory before a patient can move out of the acute phase of treatment.

Treatment programs should have arrangements in place to provide referral for hospitalization on short notice (see section later in this chapter on [Hospitalization of Methadone Patients](#)). In the absence of linkages to available resources, case management between the referring physician and hospital can facilitate this process. As in the case of psychiatric problems, stabilization of acute conditions and the institution of ongoing care for chronic conditions are mandatory before a patient can move out of the acute phase of treatment.

Legal Problems

In communities where jails and prisons do not allow opioid substitution therapy, it is important to address a patient's legal problems as soon as possible after treatment is initiated. Ongoing criminal activity may result in a patient's abrupt removal from the community -- and from opioid substitution therapy. On behalf of those who are on probation or parole, program staff should make efforts to cooperate with criminal justice agencies. Staff can thus help clients to avoid incarceration, if appropriate, by making continued treatment one condition of probation or parole.

Basic Needs

Patients' needs for basic necessities such as food, clothing, housing, and safety should be determined and referrals made to appropriate agencies. At the time of treatment entry, the chaotic lives led by many patients with opioid addiction often create legal, financial, and safety concerns that threaten survival. Homeless individuals should be referred to transitional shelters until more permanent housing can be secured.

Studies show that ease of access to the treatment facility is a predictor of retention in methadone programs ([Condelli, 1993](#)). Transportation problems may be addressed by introducing a new patient to other patients. It may also be helpful to keep a small transportation fund at the treatment site for new patients who lack resources or for emergency situations.

Treatment providers can help patients determine the extent of debts, financial or otherwise, that they may have accumulated in response to legal problems. They can also help patients deal with threats to their safety, giving special attention to threats from drug dealers or other individuals to whom they owe money. A legal advocate, eligibility case manager, or social worker can be very helpful during this phase in identifying critically needed financial resources. Linkage with a law firm that provides *pro bono* services can also be helpful.

Before a patient can be appropriately moved out of the acute phase of treatment, his or her basic need for food, clothing, shelter, and safety must be provided. The patient's living situation, if not

entirely drug free, should at least be relatively stable and secure if treatment is to move beyond the acute phase of crisis management.

For transition from the acute phase into the rehabilitation phase, patients should also begin to develop skills to remove themselves from situations in which drug use is inevitable. If a patient is unable to gain this level of control, short-term inpatient treatment may be indicated.

Therapeutic Relationship

Some patients may initially view methadone treatment as a short-term solution to opioid addiction ([Lipton et al., 1992](#)). Other patients may believe that methadone has deleterious side effects and that it is almost impossible to detoxify from this medication ([Beschner and Walters, 1985](#); [Goldsmith et al., 1984](#); [Hunt et al., 1986](#); [Magura et al., 1993](#)). These and other myths must be dispelled before meaningful treatment can begin, as they may influence treatment engagement and compliance.

In addition to correcting misconceptions about treatment, the major task of the staff, particularly the treatment counselor, is to begin to educate patients about the goals of methadone treatment, the program, and the benefits that are possible as a result of compliance. The first step in this process is to build a relationship of trust. Simple psychotherapeutic listening techniques elicit the patient's views and feelings about his or her relationship with the program and the treatment providers. Providers can help patients create their own support systems by encouraging them to be involved in appropriate social and recreational activities.

Positive reinforcement of the patient's treatment engagement and compliance is important in eliciting commitment to the therapeutic process. The Center for Substance Abuse Treatment (CSAT) has published a manual *Treatment of Opiate Addiction With Methadone: A Counselor Manual*, which addresses the importance of the therapeutic bond between counselor and patient.

The treatment provider can help the patient make a commitment to the treatment process by

- Pointing out the negative aspects of the patient's former situation
- Identifying the benefits of treatment in terms of financial advantages, improved self-esteem, and enhanced sense of well-being
- Exploring and clarifying the patient's goals in treatment.

Patients should be introduced to key staff members of the treatment program as early as possible to foster an atmosphere of safety, trust, and familiarity. Relationships with other patients can also increase the patients' level of comfort within the program. During scheduled appointments, treatment providers should minimize waiting times whenever possible to demonstrate that patients' time is valued. In addition, when the provider remains flexible and available during acute situations, he or she contributes to the patient's sense of security.

Key signs of the beginning of a positive therapeutic relationship include regular attendance at group and individual counseling sessions and positive interactions with treatment providers. Signs that patients are progressing toward the next phase of treatment include their

demonstrating compliance with the recommended treatment and then beginning to define and focus on the goals of treatment. Khantzian and associates did important work in developing effective therapeutic interventions for substance abusers ([Dodes and Khantzian, 1991](#); [Khantzian et al., 1990](#)). Measures of therapeutic helpfulness, which can be used as indicators of the strength of the therapeutic relationship, were developed by [Simpson and associates \(1995\)](#).

Motivation and Patient Readiness

Patient motivation to engage in treatment is a predictor of early retention ([Simpson and Joe, 1993](#)). The treatment provider may encounter obstacles to the development of self-motivation arising from negative attitudes toward treatment. Some of these attitudes may arise from past experiences, such as negative relationships with treatment staff, introduction of methadone treatment without needed support services, and inadequate methadone dosing.

Other potential obstacles to effective treatment include patients' ambivalence about giving up illicit drug use and fears of making major life changes. As mentioned above, many opioid users have mistaken beliefs about methadone and its effects, beliefs that can be serious obstacles to entering treatment. Even positive life changes can cause anxiety and stress when a patient is confronted with unfamiliar attitudes and situations. Several strategies have been developed to use the counselor-patient relationship to increase patient motivation ([Miller and Rollnick, 1991](#)).

Counselors should explore and openly address patients' past negative treatment experiences. It is helpful to suggest that many factors may have been responsible for such experiences and that these factors may no longer be as relevant as they once were. Emphasis should be placed on making a fresh start, letting go of old grievances, and focusing on current realities and goals. It may also help to acknowledge that the treatment staff may not have been as helpful as they could have been on previous occasions. To address patients' ambivalence about giving up drugs, providers should stress the benefits of methadone treatment in terms of preventing needle-borne infections, avoiding arrest and incarceration, and gaining peace of mind and relief of concerns over obtaining the next fix. Patients must be encouraged to recognize that, rather than being controlled by methadone, they can be empowered to gain better control over their addiction.

During scheduled appointments, treatment providers should minimize waiting times whenever possible to demonstrate that patients' time is valued. In addition, the provider's remaining flexible and available during acute situations contributes to the patient's sense that he or she can rely on the provider.

A commitment to the treatment process may be manifested by the patient's acknowledgment that his or her addiction is a problem. Before moving out of the acute phase, the patient must be motivated to make changes in his or her lifestyle and to address issues surrounding drug use.

Rehabilitation Phase

The primary goal of the rehabilitation phase of treatment is to empower patients to function in the major life domains. The methadone dosage must be stabilized at a comfortable level prior to entering this phase. During the rehabilitation phase the patient undertakes efforts to become a responsible, functioning member of society.

[Exhibit 3-3](#) summarizes the clinical issues that should be addressed during the rehabilitation phase, strategies for addressing them, and indicators for the transition from rehabilitation to the stabilization phase.

Early in the rehabilitation phase, treatment providers can assist or refer patients who need help with legal, educational, employment, and financial problems. If not addressed with high-quality services, these problems can result in patients' dropping out of treatment ([Condelli, 1993](#)). As described in the previous section, serious problems that threaten a patient's continued treatment, such as ongoing criminal activity and serious financial problems, should be addressed as soon as possible after treatment is initiated.

In the rehabilitation phase, efforts should begin toward productive participation in constructive activities such as full- or part-time employment, education, vocational training, childbearing or homemaking, or volunteer work.

Alcohol and Illicit Drug Use

Continued use of alcohol and other abusable substances, including nonopioids such as cocaine, amphetamines, benzodiazepines, and sedatives, poses obstacles to patient progress in any phase of treatment. During the rehabilitation phase, use of illicit drugs and alcohol may even precipitate a patient's regression to the acute phase. A previous Treatment Improvement Protocol (TIP) *State Methadone Treatment Guidelines* has a chapter on treating alcohol and other drug use in methadone patients, while this TIP provides only a brief overview.

Continued use of opioids must also be identified and adequately addressed to discourage the use of other drugs ([Dunteman et al., 1992](#); [Fairbank et al., 1993](#)) and prevent relapse. The frequency of urinalysis during this phase should depend upon the patient's progress in treatment. Once a patient is stabilized and is progressing well in the rehabilitation phase, with a series of negative urinalyses, the frequency of random urinalyses can be decreased to once or twice a month. Such decisions should be part of the overall treatment plan.

In the rehabilitation phase, efforts should begin toward productive participation in constructive activities such as full- or part-time employment, education, vocational training, childbearing or homemaking, or volunteer work.

Behavioral contracting is a useful strategy to address continued drug use in the rehabilitation phase ([Chambers et al., 1972](#); [Condelli et al., 1991](#); [Glosser, 1983](#); [Stitzer et al., 1986](#); [1992](#)). Essentially, this strategy requires the patient and treatment provider to identify and discuss treatment goals and expectations. Generally, the patient is then asked to sign an agreement that specifically outlines the objectives to be achieved, the behaviors to be avoided, and the consequences that will occur if the patient fails to comply with the agreement. To be effective, the details in such a behavioral contract must be worked out with the patient and mutually agreed upon.

Strategies for reducing various types of drug use among methadone patients have been described, including the use of disulfiram (Antabuse), prescribed as a deterrent to alcohol use; short-term inpatient treatment for detoxification to achieve stabilization; and intensified treatment services, such as more individual and group counseling sessions ([Kosten, 1991](#); [Kreek, 1991](#)). Other strategies include confrontation of negative behaviors and use of unprescribed drugs ([Chambers et al., 1972](#)) and provision of positive incentives in the form of take-home medication and recognition of progress ([Stitzer et al., 1992](#)).

In the rehabilitation phase, information about outside support groups that was first introduced during the acute phase should be periodically reviewed. Providers should also cultivate relationships with churches and community groups to provide support and facilities for methadone patients and, in the process, to educate the community and dispel myths about methadone.

To be eligible for transition from the rehabilitation phase, patients should be able to identify relapse triggers that remain after some of the more troublesome ones have been eliminated during the acute phase. Examples of triggers are boredom, passing by specific locations, spending time with specific individuals, having unresolved family problems, or experiencing psychiatric symptoms. Emphasis should be given to helping patients develop and maintain coping skills to deal with these triggers ([Sandberg and Marlatt, 1991](#)). These skills often involve anticipating responses when confronted with relapse triggers and rehearsing appropriate responses with the help of the counselor. A related and very important activity is to begin to make proactive changes in lifestyle and circumstances that will reduce the chances for relapse.

Discontinuation of all illicit drug use is mandatory by the end of the rehabilitation phase. Continued heavy alcohol use that is problematic and interferes with functioning will prevent the patient from moving beyond the rehabilitation phase and, for some patients, will require return to the acute phase.

Ongoing Health Concerns

Opioid users admitted to methadone programs are those who are at a notably increased risk of HIV infection and acquired immunodeficiency syndrome (AIDS), multidrug-resistant tuberculosis, and other infectious diseases ([Chaisson et al., 1989](#); [Graham et al., 1992](#); [Novick et al., 1990](#); [Schoenbaum et al., 1989](#)). They may also have chronic medical conditions such as diabetes, hypertension, or seizure disorders that require them to be referred for ongoing

treatment. In addition, many opioid users neglect dental care. Once heroin use is reduced, they may experience dental pain because the pain-killing effects of opioids have been eliminated.

In general, medical care for methadone patients should be identical to that provided for other patients. In some cases, however, dosages of medications for medical conditions may need to be adjusted because of interactions with methadone. For example, Dilantin (diphenhydantoin, phenytoin) and rifampin both tend to lower serum methadone levels and may thus require the methadone dosage to be adjusted upward. Onsite primary healthcare is optimal. When inadequate resources prohibit onsite medical services, linkages to other services should be in place. A holistic approach addressing all aspects of the patient's health will facilitate attention to neglected medical problems. Education and training about diet, exercise, personal hygiene, and smoking cessation are important. The counseling staff can use printed educational material or videotapes to present these messages.

Continued heavy alcohol use that is problematic and interferes with functioning will prevent the patient from moving beyond the rehabilitation phase, and for some patients, will require return to the acute phase.

Patients must adhere to medical care for chronic diseases and such conditions must be under control before patients can be considered for transition to subsequent phases of treatment. Improved overall health status, as well as improved dental health and hygiene, is a criterion for transition to a subsequent phase of treatment.

Employment and Other Income-Related Issues

Some of the most difficult obstacles faced by patients attempting to stabilize their lifestyle include unemployment and inadequate funds for living. Poor reading skills and lack of education contribute to the difficulties they face in obtaining stable employment. Employment opportunities in the patient's community may be lacking, even for individuals who are not handicapped by a history of AOD use.

Research suggests that males with less than a high school education have particular difficulty in negotiating for and obtaining high-quality social services ([Condelli, 1993](#)). Access to services may be a problem for many patients, both males and females, who have been addicted to drugs for years. These individuals should be targeted for educational, literacy, and vocational programs to equip them with the skills necessary to function independently. Included in these programs should be education and training about budgeting personal funds and setting up bank accounts.

Ideally, treatment programs should provide onsite counseling for the general equivalency diploma (GED). This service is rarely available onsite because of resource limitations. Therefore, a program should be able to make referrals to local adult education programs. Local businesses and industries can be encouraged to set up apprenticeships or entry-level positions. Efforts can

be made to bring together business, industry, and government leaders to set up income-generating business enterprises that can provide clients with job skills and create opportunities for their entry into the job market.

By the end of the rehabilitation phase, patients should be employed, actively seeking employment, or involved in a productive activity such as school, childrearing, or regular volunteer work. It is most important that patients have a stable source of legal income, whether from employment or other sources, to ensure that they will not resort to drug dealing or other criminal activities.

Family Relationships and Social Supports

No family can escape the stress and conflict that are brought on by another family member's addiction to drugs. Broken trust, disappointment, anger, and conflict are the realities that patients in treatment must come to face during the rehabilitation phase. Many of these individuals have been cast out of their families and have been surviving in the absence of a family support system.

During the rehabilitation phase, the counselor should help the patient build social supports and relationships, as well as rebuild and heal what are often severely damaged family relationships. The patient can gain social support by becoming involved in community or church groups or by joining a fellowship or a recreational or other peer group. It is important for these groups to understand and accept methadone therapy so that patients are not stigmatized. Increased involvement in family life should also be encouraged, in the absence of major family conflicts or dysfunction that might impede the patient's progress in treatment.

In addition, family problems that may have contributed toward the addiction will often emerge in the context of counseling during the rehabilitation phase. In such cases, staff must help patients attempt to come to terms with the impact of these traumatic family histories. Referral for family therapy may be appropriate in some cases.

Transition out of the rehabilitation phase requires that patients have a social support system in place that is free of major conflicts. Another positive indicator for transition emerges when the patient assumes increased responsibility for dependents (such as reliably paying or providing child support).

Legal Problems

Criminal charges, custody suits, and ongoing illegal activities are among the legal issues faced by many patients in treatment. Any of these problems can easily precipitate a relapse to illicit drug use, and all must be addressed as thoroughly as possible.

Counselors may have to probe into personal legal issues such as custody status and obligations. Many patients ignore these issues during periods of addiction; however, these issues may pose a serious threat to ongoing recovery. Patients should be encouraged to take responsibility for their own legal problems. The counselor may need to help the patient overcome guilt, fear, or uncertainty in relation to these problems. In addition, the treatment program must ensure that

patients have access to adequate counsel to handle their legal problems. These services are often provided by the public defender's office.

It may be difficult for some patients to extricate themselves from continued illegal activities, for either economic or social reasons. Nevertheless, efforts must be made to identify obstacles to eliminating these activities and finding ways to replace them with constructive, legal activities. All major legal problems should be resolved -- or be in the process of resolution -- and all illegal activities should cease before patients can move beyond the rehabilitation phase.

By the end of the rehabilitation phase, patients should be employed, actively seeking employment, or involved in a productive activity such as school, childrearing, or regular volunteer work. They must have a stable source of legal income from employment or other sources to ensure that they will not resort to drug dealing or other criminal activities.

Psychiatric Problems

Depression, anxiety, and insomnia are common in patients undergoing treatment for opioid addiction in any phase of treatment. As discussed earlier, these problems may pose obstacles to progress in treatment. Complaints of boredom are often a signal of depression. A wide range of other psychiatric problems may emerge during methadone treatment and may need to be addressed concomitantly with problems of substance use.

Patients should be taught coping skills to deal with frustration, anxiety, and boredom. Treatment staff should provide individualized care and should be sensitive to each patient's mental health status. Particular problems should be identified early and referrals made to appropriate resources. When indicated, a referral should be made for psychotropic medication, and patients' psychiatric status and use of medications should be evaluated on an ongoing basis. Because of the abuse potential of benzodiazepines, caution should be used when prescribing this type of medication ([see Chapter 4](#)). Anxiety disorders in this population have been effectively treated using tricyclic antidepressants rather than benzodiazepines. The latest edition of the *Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition* (DSM-IV) ([American Psychiatric Association, 1994](#)) describes a wide range of substance-induced psychiatric disorders and presents guidelines for determining when symptoms represent an independent disorder.

Before a patient can move out of the rehabilitation phase, psychiatric problems must be alleviated or stabilized. Although many psychiatric symptoms may continue to arise throughout the course of a patient's life, he or she should have adequate coping skills to prevent these symptoms from precipitating a relapse to drug addiction.

Finally, it is important to note that in many cases, when patients report persistent difficulties in several life areas, such as family and social relationships and employment, they may have a personality problem. Often, the patient is not aware of the role of his or her personal style in

creating problems. The patient's irritable behavior or suspicious, aggressive attitude may create a host of problems. Other personality problems that have been described in this population include low self-esteem and self-confidence, low tolerance for distress, impaired regulation of emotion, chronic anxiety and anger, and antisocial attitudes. Often these serious and disabling personality problems do not meet the diagnostic criteria for psychiatric disorders.

Observation and interaction with the patient over a period of time is often required to detect personality problems. Information from family members, employers, probation and parole officers, and others may be needed to clarify the problem. Most patients with these kinds of problems are not interested in or accessible to psychotherapy. A long-term therapeutic relationship with an understanding counselor can sometimes help them gain insight. Counselors working with these types of patients can be greatly helped by periodic psychiatric consultation. A previous TIP in this series, *Assessment and Treatment of Patients With Coexisting Mental Illness and Alcohol and Other Drug Abuse*, provides guidelines for working with AOD-abusing patients who have been diagnosed as having personality disorders, especially antisocial and borderline personality disorders.

Supportive Care Phase

After meeting the criteria for transition out of the rehabilitation phase, patients enter a phase in which they receive mainly supportive care. During this phase, most patients begin to receive take-home medication for longer periods and have less frequent contact with treatment staff. As the patient is getting ready to receive take-home medications, it may be a good idea to increase the frequency of urinalyses for a brief period. Similarly, once take-home privileges are granted, more frequent urinalyses during the initial stages may help the patient maintain progress.

After remaining abstinent (as confirmed by negative urine tests) for a specified period, some patients may be considered for transition into medical maintenance or medication tapering (medically supervised withdrawal from methadone). The period of time that a patient should remain in supportive care is entirely dependent on his or her individual needs. The domains and issues described above for ongoing assessment during the acute phase and rehabilitation should continue to be assessed at least quarterly to determine whether the patient is eligible and appropriate for transition into medical maintenance or methadone tapering.

Some patients may have stopped opioid use and demonstrated compliance with program rules, but have not made progress in other areas. Although they may be doing well in treatment, these patients need the ongoing support and pharmacotherapy provided by the program. They are ineligible or inappropriate candidates for either medical maintenance or methadone tapering, even after an extended period of time in supportive care. These patients should remain in the supportive care phase, receiving take-home medication and a reduced level of services in accordance with their needs. This option is usually appropriate for patients who are functioning relatively well with methadone treatment but who have mild to moderate problems that make them poor candidates for the markedly reduced level of services associated with medical maintenance or for the reduction in methadone dosage that is part of tapering.

Medical Maintenance Phase

Patients who have achieved a high degree of stability and are able to function effectively but who continue to need methadone to maintain this level of stability can be considered for medical maintenance. In this phase, patients can maintain stability on methadone and have a lifestyle that does not revolve around frequent visits to the clinic. Patients receiving medical maintenance typically are seen by their counselor or therapist once or twice a month and receive up to 6 days' supply of take-home methadone.

Some patients may be doing well in treatment, while remaining ineligible or inappropriate for either medical maintenance or methadone tapering, even after an extended period of supportive care. These patients should remain in the supportive-care phase, receiving take-home medication and a reduced level of services in accordance with their needs.

If the patient remains stable, productive, and drug free in this phase for several months or longer, the amount of take-home medication can be increased to a 2-week supply under some circumstances. Under current regulations, such a schedule is an exception and must be approved in advance by the methadone monitoring office of the Food and Drug Administration (FDA). Two-week take-home doses must also be approved by the State Methadone Authority. When dispensing take-home medication, it should be kept in mind that patients can deteriorate quickly, and thus regular visits to the clinic and urine tests are important parts of treatment during this phase.

The following criteria should be considered to determine a patient's eligibility for medical maintenance:

- Number of years in methadone treatment (at least 3 years under current FDA guidelines)
- Elimination of drug use for at least 1 year
- Noninterfering alcohol use (as assessed by use of the CAGE questionnaire, liver function test results within normal parameters, and leukocyte and erythrocyte elevations or decreases)
- Stable living conditions in a drug-free environment
- Source of stable income
- Involvement in productive activities (employment, school, volunteer work)
- No criminal or legal involvement (such as facing charges) for the last 3 years; not on parole or probation
- Adequate social support system and absence of significant psychiatric problems.

In addition, ongoing evaluation of the domains outlined in the descriptions of the acute and rehabilitation phases should take place during medical maintenance. Also recommended during this phase are random urine testing and random callbacks of medication. Callbacks involve requesting patients to bring in their remaining supply of take-home medication once every 3 to 6 months. This procedure allows treatment staff to take an inventory of medication to ensure that it

has not been diverted to others. However, such callbacks are not required by FDA regulations. If evidence of diversion is found, the patient should return to the appropriate earlier phase of treatment. Reinstatement into medical maintenance should not be implemented until program staff have closely observed the patient over an extended period (3 to 12 months or longer) in the appropriate earlier phase, and the patient has again demonstrated the required level of progress in treatment and appropriateness for medical maintenance.

Some patients may need indefinite or lifetime methadone maintenance, along with concurrent psychosocial and rehabilitative services. Some long-term stable patients can eventually be managed on lower dosages (20-60 mg), with fewer side effects than the higher dosages required at the start of treatment. Others may need to continue taking the same dosage of methadone but may not require ongoing rehabilitative services. These patients may be appropriate for medical maintenance, and they should be permitted to continue in this phase indefinitely provided they continue to meet its inclusion criteria.

Tapering and Readjustment Phase

Tapering

Most patients who choose to detoxify from methadone do so gradually. Successful rapid detoxification has been reported using naloxone to precipitate withdrawal, and clonidine to suppress acute symptoms; the patient is then inducted onto naltrexone ([Kleber et al., 1987](#); [Resnick et al., 1976](#)). *Tapering* is a term commonly used to describe the gradual reduction and elimination of methadone treatment. *Medically supervised withdrawal* is another term for this process.

In determining patients' eligibility for methadone tapering, their preferences and desires should be taken into account, with the understanding that they can return to their previous methadone dosage if tapering is not successful. Some level of discomfort during this process is inevitable, even if the dose is reduced very slowly over a period of months. A dose of 20 to 30 mg is the level below which symptoms are usually most problematic.

As medication is being tapered, services should be intensified in the form of increased monitoring of behavioral and emotional signs and increased counseling sessions. A patient being considered for methadone tapering should be sufficiently motivated to undertake this process, with the intensified counseling and increased participation in therapy sessions that it entails. Putting pressure on patients to enter this phase of treatment can have very negative results.

Counseling on the issue of tapering may consist of helping the patient to differentiate between excessive or even phobic fears of withdrawal symptoms ([Milby et al., 1987](#)) and the normal concerns that are a part of detoxification. Examples of the former are fears that one cannot live without methadone, or excessive anxiety at even the thought of detoxification. Normal concerns include worry about relapsing, how to structure activities when daily clinic attendance is no longer necessary, and how to create support for a drug-free lifestyle in the absence of regular ingestion of methadone.

In addition to physiological symptoms associated with detoxification, many patients develop a psychological dependence on the treatment program. Issues regarding loss of support may arise. These problems are usually identified in the early phases of detoxification or even before it begins.

The risk of relapse during and after tapering is significant, owing to the physical and emotional stress involved in attempting to discontinue methadone treatment. Patients should be strongly encouraged to discuss any difficulties they experience with tapering and readjustment so that appropriate action can be taken if this approach fails and relapse can be prevented. The patient should be encouraged to return to a previous phase if it is indicated at any time during tapering.

Important factors in a decision to taper medication include

- The patient's wishes and preferences
- The patient's level of motivation
- Length of addiction
- Results of previous attempts at tapering
- Family involvement and stability.

Withdrawal and Postwithdrawal Symptoms

Withdrawal symptoms such as insomnia, anxiety, cravings, or dysphoria are common, and the patient should be told to expect these symptoms during tapering, especially when lower dosages are reached (below 20-30 mg a day). Patients should be instructed about the normal course of these symptoms and the importance of tolerating them without recourse to opioid use. Several options exist for the amelioration of these symptoms. Medication can be tapered more slowly, lengthening the intervals between decreasing dosages, or the current dosage can be held at a steady level until symptoms abate. Other medications can be used to address specific symptoms. Clonidine may be instituted to control generalized withdrawal symptoms, both during or after methadone treatment. However, it should be used with caution because of its ability to reduce blood pressure.

In some cases single, low methadone doses (5 to 10 mg) can be given once or twice after completing the taper to reduce the intensity of symptoms and give the patient temporary relief from the peak of symptoms that occurs during the several days following discontinuation of daily methadone. Acupuncture has also been used to address withdrawal symptoms during methadone tapering, although its efficacy has not been adequately evaluated as of this writing ([see Chapter 4](#)). Finally, inpatient treatment may be indicated for addressing withdrawal in some patients, while others may participate in intensive outpatient rehabilitation.

For a minority of opioid-addicted persons, use of opioids helps reduce relapse to an underlying psychosis. In the past, the use of opioids and opioid blockers in the acute treatment of schizophrenia was explored (unsuccessfully) because clinicians had observed these antipsychotic effects. However, opioids seem able to help stabilize remissions in people whose acute psychotic symptoms have been controlled. Psychiatric assessment should be ongoing throughout all treatment phases.

Readjustment

Patients who complete tapering from methadone enter a period of readjustment. The reduced contact with the clinic often creates anxiety. Additional counseling is usually needed at this time. Emphasis should be placed on reinforcing the patient's coping and relapse prevention skills. The patient's primary goal during readjustment is to develop greater self-sufficiency and to create and maintain a balanced, stable, and productive lifestyle. Participation in self-help or support groups is continued during the readjustment period as dependence on the treatment program is gradually reduced. After successful completion of tapering, some patients may be helped by continued naltrexone therapy, an effective, long-lasting opioid antagonist that will block opioid effects for 2 to 3 days when given in appropriate doses. It may help motivated patients remain opioid free by creating a chemical barrier and behavioral disincentive.

Special attention and support should be provided during the first 3 to 12 months following medically supervised withdrawal, when most relapses occur. Support should be focused on fostering self-sufficiency and reinforcing the goals of treatment. Other strategies to help patients after the completion of tapering include

- Problem-solving counseling approaches
- Reinforcement of positive behaviors and attitudes
- Maintenance of an open-door policy to maximize
- the availability of counselors and providers
- Use of the patient's support system, such as self-help groups, to benefit the recovery process.

Reversion to Methadone Treatment

Even under the best of circumstances -- with a highly motivated and stable patient and with strong family and social support systems in place -- there is no guarantee that tapering will be successful. Because many patients find that they cannot complete tapering, all patients in this phase should be carefully counseled to understand that a return to a higher methadone dosage does not represent a failure, either of the treatment program or of the individual. A return to a previous phase may simply be an indication that the ongoing use of methadone may be more appropriate, at least for the present time. For many patients, the optimum outcome that can be achieved is continued functioning on methadone. Patients also need to understand that tapering can be restarted at any time, when both patient and staff feel it is appropriate.

Indicators for Transition

Successful discontinuation of methadone is the key indicator for transition from the tapering phase. Another primary indicator for transition is the patient's transformed identity. Development of a positive self-view as functioning well without methadone and adoption of a socially productive lifestyle without involvement in drugs or alcohol is critical to the completion of this phase and to continued recovery. The absence of signs and symptoms of dependence or abuse, as defined by the DSM-IV or the *International Classification of Diseases, Tenth Edition* (ICD-10) ([see Chapter 2](#)), and negative urinalyses and breath tests for nonprescribed abuseable substances are criteria that must be met before the tasks and goals of this phase are complete. Continued

participation in self-help groups is often helpful for the reinforcement of coping and relapse prevention skills. Finally, the patient should have achieved and maintained relative stability in all of the life domains discussed above.

Aftercare Phase

Aftercare is a phase that follows successful tapering and readjustment; it is based on clear evidence that recovery is well under way. As discussed above, the patient has adopted a socially productive lifestyle, is no longer involved with drugs or alcohol, and has demonstrated appropriate coping skills over a period of at least 1 year. Persons in this phase are often involved in regular attendance at self-help groups, and regular treatment is no longer necessary, except to keep open contact with treatment providers and to ensure that recovery continues. During this phase, appointments may be scheduled every 1 to 3 months, although many programs prefer that patients maintain monthly contact. The period for which patients are monitored in aftercare varies among programs, but many consider 6 to 12 months to be a reasonable time.

Persons in the aftercare phase are often involved in regular attendance at self-help groups, and treatment is no longer necessary except to keep open contact with treatment providers and to ensure that recovery continues.

Some patients may not need aftercare services, preferring a complete break from the clinic. Others may need more extensive aftercare and a referral to a nonmethadone outpatient treatment program. As with any chronic condition, an unfortunate tendency exists for care providers not to see patients until their condition is out of control again (a full-blown relapse). It is helpful to develop a structure to reduce the chances of such an adverse event. Periodic recall of patients, perhaps annually or semiannually, is one effective method that some programs use to keep in touch with patients. Another way to maintain regular contact with patients, if resources permit, is to set up a monthly or quarterly "alumni" group that brings together former patients of the program. As in the treatment of all addictions, treatment effectiveness is usually improved if the patient becomes involved in self-help groups, such as Narcotics Anonymous and Methadone Anonymous.

Transition Between Phases, Discharge, and Readmission

Transition Between Phases

The treatment system must be flexible enough to allow for transition from one phase to another according to the patient's progress. For example, crises or stressful life circumstances, such as financial debt or psychosocial stressors, may overwhelm a patient who resumes drug use in the belief that he or she is now "cured" and can control this behavior. Patients are often presented with opportunities for opioid use in their social environment. They may be tempted to test

themselves to find out whether they are able to use opioids only once. Such individuals often rapidly regress to addictive behaviors that warrant transfer to the acute phase.

Occasional relapses to drug use may not require that a patient reenter the acute phase, but intensified counseling, loss of take-home privileges, dosage adjustments, or all of these interventions may be needed. If a patient is in the medical maintenance phase or the tapering and readjustment phase, a relapse almost always requires an immediate change of phase. In such cases, the patient would be considered in the rehabilitation phase once again. After providing evidence that the problems are well under control, the patient may be able to return to supportive care or medical maintenance.

A simple checklist, based on seven basic spheres of functioning ([see Exhibit 3-4](#)), that can be completed by case managers on a regular basis may facilitate monitoring of treatment progress. Factors warranting consideration of transfer to another phase can be recorded and periodically reviewed. Such a record can also be referred to in later treatment phases for information about a patient's earlier treatment experience.

Voluntary Discharge

If a patient-requested voluntary discharge is against the advice and judgment of the treatment provider, a note should be made to that effect in the discharge plan. If the patient has made substantial progress and is in good standing with the program, efforts should be made to determine why he or she is requesting a discharge. Patients who are using heroin or other illicit drugs should be strongly discouraged from undergoing voluntary detoxification.

Efforts to resolve problems should be made to retain the patient in treatment. A referral can be made to another program that is more appropriate for the patient's needs at that time. Patients with a history of failed attempts at medically supervised withdrawal who request discharge should be counseled and educated about their risk of relapse and encouraged to stay. It may also be helpful to review the patient's treatment and relapse history to help the patient realistically assess his or her situation.

When these measures fail and a patient insists on leaving treatment, the discharge plan should allow him or her to reverse the decision at any point. The patient should be given the opportunity to return after discharge, and reentry into the program should be made as easy as possible.

Involuntary Discharge

Decisionmaking

All programs must develop, disseminate, and consistently enforce guidelines for the management of patients who fail to comply with program rules. Program rules and the terms under which patients can be involuntarily discharged from the treatment program should be explained clearly to the patient. These rules should also be posted within the clinic, along with a description of the mechanism to appeal such decisions. Staff members should identify problems as they emerge and respond to them promptly.

The response must be tailored to the degree of severity of the problem. Patients should not be disciplined by having their methadone dosage lowered, nor should they be rewarded for good conduct by having the dosage raised. Programs are encouraged to develop nonpunitive ways to set limits and to contain problematic behavior. However, in some cases, involuntary discharge becomes necessary. Program staff are responsible for ensuring the safety and security of all patients and employees. This responsibility entails a clear need to maintain order, safety, and discipline within the building and grounds of the treatment program.

The terms for involuntary discharge vary among programs. Infraction of some rules may mean mandatory discharge, whereas other cases must be clinically evaluated in light of individual circumstances. Generally, behaviors that threaten the safety of the staff, patients, or the integrity of the program lead to automatic discharge. Examples are fighting, making threats, bringing weapons into the program, falsifying urine specimens, drug dealing, or diverting methadone. If the offense is not one for which suspension is mandatory, the patient's motivation and progress in treatment should be taken into account in determining whether he or she should be discharged, placed on probation, or merely warned. No patient should be discharged for minimal drug use.

Each treatment program must decide what level of drug use, over what period of time, is grounds for discharge. This decision will vary among programs. Some may allow only minimal drug use, whereas others may tolerate some repeated use unless the patient fails to comply with the treatment or counseling program or breaks program rules. Other clinics operate on the philosophy that, regardless of the level of drug use, patients should be kept in treatment, where they can be continually encouraged to stop their drug use.

It may be necessary to set some limits on patients who continue illicit drug use. The types of drugs used and their potential for serious adverse effects should be considered. For example, a patient who is dependent on large doses of alcohol, barbiturates, benzodiazepines, or other nonbenzodiazepine sedatives is at high risk of overdose or accidental injury and should immediately be considered for transfer out of methadone treatment until the sedative dependence is better controlled. Another important consideration in cases of unremitting drug use is its impact on other patients. A program's excessive tolerance of continued illicit drug use or total reluctance to set limits on use can diminish patients' respect for the overall program, as well as the respect of the community and other agencies.

Programs should consider for discharge only those persons judged to be "nonresponders" to methadone treatment despite the best efforts of the staff. If these patients do not keep appointments, do not comply with other aspects of the program, and do not put forth even minimal efforts to work with the staff toward appropriate treatment goals, discharge or transfer to another treatment modality is probably indicated. Essentially, such cases involve individuals who are not trying, whose progress in reducing drug use and achieving other goals is minimal or absent, and who would probably be doing about as well even without treatment.

However, it is important to note here that discharge in cases of treatment nonresponse is the last step in a long series of careful assessments and interventions. When a patient fails to improve, the first response should be to review the treatment plan and intensify treatment to match the patient's clinical status. Most programs have at least a limited capacity to intensify treatment by

adding an extra 30-minute session of individual counseling or by requiring a group session weekly. Seeing poorly performing patients more frequently, even for less time each session, enhances the overall structure of treatment, which is a critical factor for many patients in opioid substitution therapy.

In any case, the decision to discharge for drug use should not be made solely on the results of urine testing; rather, a range of factors should be considered. Each clinic should set standards and be consistent, keeping in mind the benefits and drawbacks of the chosen approach. Clinics that are more tolerant may have higher rates of drug use and greater retention of patients in treatment, but they may risk fostering negative attitudes in non-drug-using patients. Programs that are less tolerant will have less drug use but may also risk losing patients who have the potential to benefit from treatment, especially over the longer term. Such patients are likely to be those with significant psychiatric or other associated problems and who may eventually respond to treatment, provided the appropriate blend of counseling and additional services can be arranged.

Another reason for involuntary discharge may be inability to continue to pay for program services. Discharge for nonpayment of program fees should be preceded by formal warnings from the program and efforts to help the patient change his or her behavior. For example, to prevent discharge for failure to pay, the patient should be advised to inform the program of impending financial problems as soon as possible. Staff will then have time to investigate other treatment, payment, or program alternatives. In any case, discharge should not occur until all efforts to secure reimbursement have been exhausted. Whenever possible, discharge should occur within the context of referral to another center with a sliding fee scale or to a State-subsidized program.

Involuntary discharge of patients who are HIV positive or who have AIDS creates a dilemma for staff. Concerns that the HIV-positive patient will resume needle sharing and transmit the virus often lead staff to ignore noncompliance issues in this patient group to retain the patient in the program. However, if staff suspect that the patient is continuing to share needles while attending the program, they also have strong concerns that ignoring noncompliance is "enabling" the patient to put others at risk. As discussed below, programs should make every effort to retain patients in treatment regardless of their HIV status. If a patient must be discharged, referrals should be made to a more appropriate level of treatment or to other substitution therapy programs. These considerations are especially important with HIV-positive patients and those with AIDS. The TIP Providing Treatment for HIV-Infected Alcohol and Other Drug Abusers provides further discussion of these issues.

Retaining Patients in the Program

Regardless of individual clinic policies, however, drug-using patients should not be allowed the same privileges (such as take-home medication) as other patients. Neither should their behavior be tolerated indefinitely without some type of intervention. Before discharging a patient for nonresponse to treatment, every effort should be made to provide the most appropriate treatment available for that individual's specific problems, and to persuade him or her to become fully engaged in treatment and to discontinue drug use. Approaches may include

- Intensive counseling
- Additional psychotherapy, pharmacotherapy, or combinations of both for psychiatric disorders
- Treatment of medical or other associated problems
- Inpatient detoxification with return to methadone treatment
- Change of counselors, if clinically indicated
- Alternative medications (for example, levo-alpha-acetyl-methadol [LAAM])
- Dosage adjustments
- Family intervention.

Discharge Procedures

If a decision is made to discharge a patient, discharge procedures should be initiated and withdrawal of methadone begun. Involuntary discharges should be made with the understanding that the patient may return to the program, provided that identified preconditions have been met, within a specified period of time. Obstacles to reentry should be minimized if the requirements are met. Even when a patient is discharged for drug use, the door should still remain open for his or her return, provided that the patient demonstrates that methadone treatment can help (for example, by doing well in another program). It may be advisable in some cases to schedule a date to invite the patient back to talk about whether he or she may reenter the program. Patients in treatment often fare better when their care is provided by a single provider group, even if treatment is episodic rather than continual.

Medical and Psychiatric Safety

Serious medical or psychiatric problems sometimes make it inadvisable or impossible for a patient to continue in a particular program. Ideally, patients benefiting from methadone therapy should be permitted to continue with this treatment in other settings, whether medical or psychiatric. Toward this end, treatment staff should work closely with other providers who treat the patient after transfer from the methadone program.

If attempts to facilitate continued medication in another setting are unsuccessful, a program of detoxification may have to be started. The facility to which the patient was transferred should make a referral back to the methadone treatment program as part of the patient's discharge plan. In such cases, the patient should be reassessed before resuming opioid substitution therapy, because his or her status may have changed.

Incarceration

Methadone treatment is almost always discontinued for patients who become incarcerated. Only one methadone maintenance program for incarcerated opioid-addicted offenders is known to exist in the United States, and that is at Rikers Island, New York City's central jail facility ([Magura et al., 1993](#)).

The treatment program should extend its best efforts to work with the penal facility and ensure that the appropriate detoxification procedures are used. Upon release from incarceration, patients who desire readmission should be reassessed to determine the appropriate treatment phase.

Readmission

Readmission to methadone treatment is a common issue that must be anticipated. [Marsh and associates \(1990\)](#) reported that among the addicted patients they studied, multiple treatment admissions occurred over a 12-year followup period, with an average of more than six program admissions for each patient, most often involving methadone treatment. Patients being readmitted, whether from the same program or from other programs, should be placed in the phase of treatment that offers the most appropriate level of care.

To determine the appropriate phase, all key domains of functioning should be assessed to identify any factors warranting the patient's placement in a particular phase. The length of time the patient has been out of treatment should be taken into account. A complete reintake assessment is likely to be in order if this period is longer than 1 month, but is probably not necessary if the patient has had a shorter absence from treatment. The patient's history of drug use and performance while outside the treatment program, as well as any legal requirements, are also important factors to consider in this decision.

Review and Appeals Processes

Opioid substitution therapy programs should have written guidelines under which cases of involuntary discharge may be appealed and examined by staff -- generally, clinical staff. Some States have developed regulations to guide this process, partly to ensure that it will be impartially conducted. In these States, the reviews and appeals are administrative rather than clinical procedures. Whether the process is regulated by the State or not, most programs have established a formal mechanism whereby the appeal is referred to consecutively higher levels of program authority. Staff members who are directly involved with the disciplinary action should not conduct the review procedure. Appeals should be handled promptly.

Clinical Issues Throughout All Treatment Phases

A variety of clinical issues arise during methadone treatment, and some may arise during more than one phase. Dispensing take-home medication and ensuring continued medication for patients who enter the hospital are discussed here.

Take-Home Medication

Medication dispensed for patients to take home may begin on a gradual basis during the rehabilitation phase for patients who meet Federal eligibility criteria. These criteria require that the person demonstrate the absence of drug use by urine testing and attend the clinic and counseling sessions regularly. Other signs of rehabilitation such as working or being in school should also be evident, and program staff must judge the patient to be responsible for taking the medication as prescribed. Although not required by FDA regulations, negative breath tests for alcohol constitute an important sign that rehabilitation is under way, and demonstration of consistent negative results is strongly recommended as a criterion for eligibility for take-home medication. The amount of medication dispensed for take-home purposes gradually increases in

accordance with program policy and FDA regulations throughout the rehabilitation, supportive care, and medical maintenance phases.

Throughout treatment, providers should monitor patients for stresses or life changes that could lead to relapse. When such stressors are identified or anticipated, more frequent clinic visits, closer monitoring, and increased support often prevent relapse. In such situations, patients who are not required to attend the clinic frequently (such as those on medical maintenance) can continue to receive their take-home medication but may be required to come to the clinic to take it or to receive additional counseling until the crisis passes. In this way, patients retain a sense of control, while providers ensure that medication is not diverted.

In supportive care, the length of time for which take-home medication is dispensed varies according to individual needs but is usually not longer than 6 days. Before a patient is considered for transition into medical maintenance, he or she has generally been receiving take-home medication in supportive care. LAAM, which has a longer duration of action than methadone, may be useful during supportive care or even earlier in treatment to limit take-home medication while maintaining the patient's contact with the clinic. (See the TIP *LAAM in the Treatment of Opiate Addiction*.)

During tapering of methadone, take-home medication is continued until lower doses are reached. At this point, patients must be seen more frequently and should be required to come to the clinic for each dose. Clinic policies concerning take-home medications during the tapering phase must be tailored to individual needs.

Hospitalization of Methadone Patients

During a medical crisis requiring hospitalization, it is important for the physician providing methadone treatment to communicate with the hospital attending physician and other members of the healthcare team. The team should be informed of the patient's methadone dosage and the date on which methadone was last received.

It is extremely important that the treating physician be aware that the patient will probably require larger amounts of medication for anesthesia, and that adequate pain relief will require that the patient receive the normal methadone dose (or its equivalent) plus additional medication. Communicating these facts to the healthcare team will usually ensure that appropriate care is administered.

In addition, the healthcare team should be advised to institute appropriate behavioral controls to prevent the patient from using illicit substances while in the hospital. These controls are especially important for unstable methadone patients who are in the acute phase of treatment. They may include limiting visitors, preventing the patient from wandering through the hospital, and scheduling regular urine drug screens. It is usually helpful to provide psychiatric consultation to medical or surgical staff, especially in the case of patients with comorbid psychiatric disorders.

Conclusions

The use of a phased model of methadone treatment assists patients in setting goals and establishing markers for progress. Each patient's needs, however, rather than the phases themselves, should dictate the specific course of treatment. The phases should simply facilitate the natural course of the recovery process.

This chapter provides a framework for a phased model of treatment that must be adapted to the needs of each patient population and treatment setting. As this model evolves, each component must undergo critical evaluation from the perspective of patient outcome, cost-effectiveness, and quality improvement so that its advantages and shortcomings can be clearly documented.

Summary of Recommendations

Recommendations of the panel are also summarized in [Exhibits 3-2](#) and [3-3](#) (see especially the columns headed "Indicators for Transition . . .").

1. Phases of treatment should be established as a dynamic continuum that allows each patient to progress according to his or her individual needs.
2. Treatment outcomes should be evaluated not solely in terms of how many phases the patient has moved through, but rather by the degree to which the patient's needs, goals, and expectations have been met by the treatment program.

Acute Phase

1. Staff should have frequent interaction with patients, should encourage ongoing dialogue concerning their symptoms, and should not take a punitive approach if drugs other than opioids are being used.
2. Independent psychiatric disorders and substance-induced psychiatric disorders should be identified and addressed.
3. Long-standing medical problems should be addressed immediately. Stabilization of acute conditions and the institution of ongoing care for chronic conditions are mandatory before a patient can move out of the acute phase.
4. Patients' needs for basic necessities such as food, clothing, housing, and safety should be determined and referrals made to appropriate agencies.
5. A patient's legal problems should be addressed as soon as possible after treatment is initiated.
6. The counselor should correct misconceptions about treatment and educate patients about the program and the benefits and goals of treatment.
7. Patients should be introduced to key staff members of the treatment program as early as possible to foster an atmosphere of safety, trust, and familiarity.
8. Waiting times should be minimized to demonstrate that patients' time is valued.
9. Counselors should explore and openly address patients' past negative treatment experiences.

Rehabilitation Phase

1. The methadone dosage must be stabilized at a comfortable level prior to entering this phase.

2. Efforts should begin toward productive participation in constructive activities such as full- or part-time employment, education, vocational training, childrearing or homemaking, or volunteer work.
3. Information about outside support groups introduced during the acute phase should be periodically reviewed.
4. Providers should cultivate relationships with churches and community groups to provide support and facilities for methadone patients.
5. Providers should help patients develop and maintain coping skills to deal with relapse triggers.
6. Medical care for methadone patients should be identical to that provided for other patients.
7. Educational, literacy, and vocational programs should be provided to help patients build the skills they need to function independently. Information about budgeting personal funds and setting up bank accounts should be included.
8. Providers should help patients gain a stable source of legal income to ensure that they will not resort to criminal activities.
9. Patients should be encouraged to take responsibility for their own legal problems.
10. Patients should be taught coping skills to deal with frustration, anxiety, and boredom.

Supportive Care Phase

1. Life domains and other issues should continue to be assessed at least quarterly.

Medical Maintenance Phase

1. Several criteria should be considered in determining eligibility for the medical maintenance phase
 - Number of years in methadone treatment (at least 3 years under current FDA guidelines)
 - Elimination of drug use for at least 1 year
 - Noninterfering alcohol use
 - Stable living conditions in a drug-free environment
 - Source of stable income
 - Involvement in productive activities
 - No criminal or legal involvement for the last 3 years; not on parole or probation
 - Adequate social support system and absence of significant psychiatric problems.

Tapering and Readjustment Phases

1. Patients' preferences and desires about tapering should be taken into account, with the understanding that they can return to their previous methadone dosage if tapering is not successful.
2. Patients should be strongly encouraged to discuss any difficulties they experience with tapering and readjustment so that appropriate action can be taken if this approach fails and relapse can be prevented.
3. Patients should be instructed about normal withdrawal symptoms and the importance of tolerating them without recourse to opioid use.
4. Emphasis should be placed on reinforcing the patient's coping and relapse prevention skills.

5. Special attention and support should be provided during the first 3 to 12 months following detoxification, when most relapses occur. Support should focus on fostering self-sufficiency and reinforcing the goals of treatment.

It is extremely important that the treating hospital physician be informed that the patient will probably require larger amounts of medication for anesthesia, and that adequate pain relief will require that the patient receive the normal methadone dose (or its equivalent) plus additional medication.

Transition Between Phases

1. The treatment system must be flexible enough to allow for transition from one phase to another according to the patient's progress.

Discharge

1. Program rules and the terms under which patients can be involuntarily discharged from the treatment program should be explained clearly to the patient.
2. Staff members should identify problems as they emerge and respond to them promptly.
3. Patients with a history of failed attempts at detoxification who request discharge should be counseled, educated about their risk of relapse, and encouraged to stay.
4. Patients who are using opioids or other illicit drugs should be strongly discouraged from undergoing voluntary detoxification.
5. The discharge plan should allow the patient to reverse the decision at any point. The patient should be given the opportunity to return after discharge, and reentry into the program should be as easy as possible.
6. Involuntary discharges should be made with the understanding that the patient may return to the program, provided that identified preconditions have been met, within a specified period of time.
7. The decision to discharge for drug use should not be made solely on the results of urine testing; rather, a range of factors should be considered.
8. Programs should consider for discharge only those persons judged to be "nonresponders" to methadone treatment despite the best efforts of the staff.
9. Drug-using patients should not be allowed the same privileges (such as take-home medication) as other patients.
10. Ideally, patients should be readmitted within 30 days to avoid their seeking admission to another program and perpetuating the revolving-door syndrome.
11. For readmitted patients, a complete reintake assessment is probably in order if this period is longer than 1 month but is probably not necessary if the patient has had a shorter absence from treatment.
12. Opioid substitution therapy programs should have written guidelines under which cases of involuntary discharge may be appealed and examined by staff.

Hospitalization

1. During a medical crisis requiring hospitalization, it is important for the physician providing methadone treatment to communicate with the hospital attending physician and other members of the healthcare team.
2. It is important to communicate to the treating physician that the patient should continue to receive his or her normal methadone dose, plus additional medication for pain relief.

Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series 20

Chapter 4 -- Treatment Elements

This chapter describes the elements of treatment necessary to develop matching strategies that meet the range of patient needs. Core services are described, including dispensing medication, counseling to help reduce substance abuse, monitoring drug use via routine urinalyses, and monitoring patients' medical and psychiatric status.

Staff from several disciplines are often employed in opioid substitution therapy programs; their varying skills are needed to develop effective matching strategies. This chapter includes descriptions of these staff members and their responsibilities. Considerations in establishing an optimal methadone dosage level are outlined. A detailed discussion is included of the effective use of counseling, behavioral treatments, and psychotherapies. Some special considerations in delivering effective treatment, such as providing childcare, ensuring access to the disabled, and preventing fraternization between staff and patients, are also addressed.

Overview: Elements of Effective Treatment

A core group of services is essential for administering opioid substitution therapy. Although the minimum requirements for basic services are outlined in the Food and Drug Administration (FDA) regulations, program requirements may vary according to State standards, accreditation requirements, and treatment guidelines. The consensus panel for this Treatment Improvement Protocol (TIP) recommends that the core services minimally include

- Assessing patients
- Dispensing medication
- Administering urine tests
- Identifying acute medical or psychiatric and neuropsychological problems when they occur
- Counseling to reduce substance use
- Evaluating and addressing family problems
- Referring patients to additional services as needed
- Performing clerical functions and keeping records
- Providing security.

All effective opioid substitution therapy programs should have these core services in place. Many opioid-dependent patients also have other problems -- medical, psychiatric, social, family, vocational, or legal -- and many have substance use disorders involving nonopioids. If unattended, these associated problems will probably hinder treatment of opioid addiction.

Staff Roles and Responsibilities

A variety of medical, other professional, and support staff have responsibilities for treating patients who enter opioid substitution therapy. Because of the increased use of the biopsychosocial framework throughout the health services field, the expertise and services provided by a wide range of professionals are increasingly valued. Having a variety of personnel with different expertise and perspectives is important to matching professionals to patients. Professionals with specialized skills greatly extend the ability of the program to provide onsite treatment. For example, nurses and physician assistants can provide ongoing treatment for patients with chronic but stable medical conditions such as human immunodeficiency virus (HIV) disease, diabetes, tuberculosis (TB), and hypertension.

The treatment team consists of

- Physicians, including psychiatrists
- Nonphysician medical staff such as nurse practitioners (NPs), physician assistants (PAs), pharmacists, and pharmacy assistants
- Nonmedical professional staff such as with bachelor's or master's degrees (social workers, psychologists, vocational and educational specialists)
- Addiction specialists and drug counselors
- Nonclinical and administrative staff (such as office managers, clerical staff, receptionists, secretaries, and advocates)
- Security personnel.

Having a variety of personnel with different perspectives is important to matching professionals to patients. Professionals with specialized skills greatly extend the ability of the program to provide onsite treatment.

The roles and responsibilities of some staff members are briefly described below.

Physicians

All opioid substitution programs are required by Federal and State regulations to have a physician who is identified as the program's medical director. The physician may be a psychiatrist or internist, must be either onsite or on staff as an employee or consultant, and must be registered to prescribe and administer methadone or levo-alpha-acetyl-methadol (LAAM) for opioid substitution therapy. The medical director may be assisted by one or more additional

physicians, who must also be registered with the State and the FDA and approved by the Drug Enforcement Administration (DEA). The medical director is responsible for the overall substance abuse, medical, and psychiatric treatment of patients in the program. For some patients who need many services, compliance may be improved if the program physician can spend sufficient time with the patient to establish a strong physician-patient relationship.

In some programs with greater resources, physicians can play a more integrated and specialized role in ongoing treatment. For example, a program physician trained in internal medicine may take a more active role in diagnosing and treating medical disorders. If the medical director is a psychiatrist, he or she can provide onsite psychiatric evaluations, and in some cases, can treat patients with comorbid psychiatric conditions or supervise others in providing such treatment. Although it may be ideal for all opioid substitution therapy programs to have a psychiatrist on staff, in many programs it is not feasible. When a psychiatrist is not on staff, the program physician's role is limited to the core functions described below:

- Assessing patient for admission and continued opioid substitution therapy and informing the patient of risks and benefits
- Evaluating the patient's initial response to methadone or LAAM and adjusting the dosage as needed
- Providing assessment and treatment (or referring patient for treatment) of associated medical and psychiatric conditions
- Supervising staff.

Medical Staff

Medical staff includes registered nurses (RNs), licensed practical nurses (LPNs), nurse practitioners, registered nurse clinical specialists (RNCSSs), physician assistants, pharmacists, and pharmacy assistants.

- Pharmacists dispense (and in some programs administer) methadone or LAAM, order controlled substances, and keep records.
- RNs and LPNs can administer these medications, maintain records, and facilitate referrals for medical and psychiatric treatment.
- NPs and PAs perform physical examinations of new patients and evaluate and treat patients for some medical problems.
- All nonphysician medical staff members consult with program staff on all aspects of patient care.

Other Professional Staff With Formal Degrees

Social workers typically have master's degrees and training in a wide range of useful skills. Depending on their background and training, they can provide

- Drug and alcohol counseling
- Psychotherapy and family therapy
- Case management
- Pre- and posttest HIV counseling

- Skills training, including job skills, parenting skills, and life skills
- Supervision of other staff who provide these services.

Psychologists have master's degrees or doctorates. Services they provide include

- Psychological testing and evaluation (doctoral level)
- Psychotherapy, including family therapy, for patients with dual diagnoses and with complicated psychiatric conditions
- Consultation to program staff about behavioral therapy strategies
- Supervision of staff.

Vocational and educational specialists usually have master's degrees and provide services such as

- Vocational assessments and making referrals
- Vocational skills training
- Assistance in helping patients obtain a general educational development (GED) certificate and in providing referrals for jobs
- Teaching good work habits.

Addiction Specialists and Drug Counselors

Most substitution therapy programs hire persons with bachelor's degrees or less formal education to serve as addiction specialists or drug counselors. Many have no training in a specific discipline but have an interest in treating addicted individuals. Many have learned drug counseling techniques through their work in methadone or other drug treatment programs or through their own recovery experiences. These persons often serve as the backbone of substitution therapy programs and in some cases provide most of the front-line care. The functions of the counselor and the importance of counseling are addressed in more detail in the section on Counseling, Behavioral Treatments, and Psychotherapy later in this chapter.

Extreme care should be taken in hiring to be certain that recovering individuals are in sustained full remission as defined by the current edition of the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV) ([American Psychiatric Association, 1994](#)). Some programs require recovering persons to be in sustained full remission for at least 3 years before being hired and to demonstrate good performance in one or more jobs.

In some programs, counselors have caseloads of 50 or more patients, well above the recommended limit of 35 discussed in [Chapter 2](#). Generally, they

- Address addiction issues and concrete problems via individual and group counseling
- Recommend adjustments in dosage and take-home schedules
- Enforce program rules
- Provide crisis intervention
- Provide case management and make referrals.

Drug counselors also have significant recordkeeping responsibilities. They play a major role in developing the initial treatment plan, monitoring its implementation, explaining the importance of treatment to the patient, updating the plan at specified intervals, and making sure the patient understands the reasons for modifications or adjustments in treatment.

There has been a trend in many programs to upgrade the qualifications of counselors and therapists to require a master's degree in clinical psychology, social work, or a related discipline. In such programs, it is important to match patients to clinicians with the specialized training and professional background to recognize and respond to more complex medical and psychiatric problems.

Administrative Staff

These team members include office managers, secretaries, receptionists, billing department staff, and security staff. They do not have specific treatment responsibility for the patient, but often provide valuable information for the treatment team. Responsibilities include operational management of programs, provision of billing, receipt of payments of clinic fees, record review, observation of milieu interactions, and telephone coverage.

The Treatment Team

Regardless of the backgrounds of various staff members, working as an integrated team is critical to delivering effective services to patients in opioid substitution therapy. Regular staff meetings and case coordination are important components of this strategy. Although it is particularly important to consider the impressions and observations of the patient's counselor and therapist, the definition of the team should not be limited to direct clinical or treatment staff. The team is made up of all individuals who interact with the patient throughout the course of treatment. This includes the program staff as well as offsite primary care clinicians, medical and psychiatric specialists, administrative and treatment staff of affiliated agencies, probation officers, attorneys, advocates, and so forth.

Effective work as an integrated team is critical to delivering services to patients in opioid substitution therapy. The team includes all individuals who interact with the patient throughout the course of treatment. This includes all program staff, as well as offsite primary care clinicians, medical and psychiatric specialists, administrative and treatment staff of affiliated agencies, probation officers, attorneys, and advocates.

Each team member plays an integral role in the delivery of services and should be considered in the treatment planning process. For example, when a treatment plan or a specific problem with a patient and his or her family is being considered, the program receptionist may have critical information. The program receptionist is the first line of communication with the patient and can observe the patient while he or she is waiting for an appointment or observe interactions with

children or family members. The receptionist may talk to the patient on the telephone and be privy to information that others may not readily obtain. Treatment providers from other agencies may have information or observations of the patient that differ from those of onsite program staff. Billing office staff may have information about how the patient handles financial responsibilities. The observations and opinions of the entire treatment team provide varied and valuable information for patient assessment and should be included in the treatment planning process. Participation of all members of the team may be critical to successful interventions.

It is important to establish careful screening procedures during job interviews to protect patients from individuals with biases and rigid or even negative ideas about opioid substitution therapy and recovery. Programs should hire staff who are flexible, educated, self-disciplined, and willing to learn, and who get along with a multidisciplinary group.

Continuing Education

Treatment programs generally employ inservice education, case presentations, supervisory sessions, and other methods to maintain and upgrade the skills of the counseling staff. In many States, addiction specialists and drug counselors are offered training courses and can obtain certification in addiction counseling. Most of these, however, provide little or no information about opioid substitution therapy. Like licensed professionals, certified addiction counselors are required to participate in continuing education to keep their certification.

Regardless of counselor status, programs should require all clinicians who provide direct services to participate in continuing education. Participation should be reviewed as part of the employee review process. Topics for continuing education might include HIV, acquired immunodeficiency syndrome (AIDS) and TB, dual diagnosis, homelessness, and counseling techniques such as motivational interventions ([Saunders et al., 1991](#)).

Supervision

Clinical supervision ensures that the clinician's work with patients is monitored; it also serves as a vehicle for ongoing training and support. Clinical supervision is particularly critical to identifying transference and countertransference issues in the treatment setting and offering management strategies.

Many individuals, irrespective of professional discipline, bring powerful countertransference issues to the treatment milieu. Countertransference refers broadly to feelings that the therapist has toward his or her patient. When recognized and analyzed, many such feelings can provide valuable insights into the patient and the therapeutic relationship. However, some countertransference feelings are irrational and not useful; they create obstacles to treatment unless they are identified and modified. One common countertransference issue among recovering individuals working in opioid substitution therapy programs is a sense that there is

only one path to recovery (generally the path that the recovering individual has taken). Some individuals may also regard patients' dependence on methadone as not legitimate or "real" recovery; they may have a punitive attitude toward patients in the program. Conversely, other staff may be overly supportive or protective of certain patients and unwilling or unable to set reasonable or appropriate limits on inappropriate behavior.

It is important to establish careful screening procedures during job interviews to protect patients from individuals with biases and rigid or even negative ideas about opioid substitution therapy and recovery. Programs should hire staff who are flexible, educated, self-disciplined, and willing to learn, and who get along with a multidisciplinary group.

Establishing a Methadone Dosage Level

Establishing an adequate methadone dosage level is crucial to eliminating illicit opioid use. Dosage determination is covered in detail in a previous TIP *State Methadone Treatment Guidelines*, and it is reviewed only briefly here. That TIP also contains valuable information about medications that interact with methadone and affect its metabolism.

Adequate dosages have been shown to be a primary determinant of retention in treatment ([Caplehorn and Bell, 1991](#)). Given this fact, two considerations merit emphasis:

- The methadone dosage, like that of all prescribed drugs, should be individualized and based primarily on the patient's response to the medication
- Methadone's effectiveness is dose dependent, and higher dosages generally are more effective than lower dosages.

The optimum methadone dosage varies widely among patients, as does the dosage of other medications that are used in psychiatry and general medicine. A number of studies have indicated that dosage levels of 60 to 120 mg per day of methadone (or its LAAM equivalent) are necessary to provide a blocking dose, the best chance of suppressing self-administration of opioids for most patients ([Ball and Ross, 1991](#); [Caplehorn and Bell, 1991](#); [Wolff et al., 1991](#)). Starting dosages for new patients are usually in the range of 20 to 30 mg per day, and the dosage is increased over a period of weeks to months to a level needed to stabilize the patient and suppress heroin use.

A few studies have examined the relationship between methadone plasma levels and treatment outcomes. They have found that levels of 150 to 200 nanograms (ng) of methadone per milliliter (ml) of blood (equivalent to a dosage of 40 to 50 mg of methadone a day) are necessary to sustain suppression of opioid withdrawal symptoms for 24 hours and that levels of 400 ng per ml (equivalent to 80 mg of methadone a day) or more are necessary to achieve narcotic blockade and better clinical outcomes ([Dole, 1988](#); [Loimer et al., 1991](#)).

These studies have also shown that plasma levels of methadone vary widely among individuals, even when oral doses are held constant. Such individual variability is also found with antidepressants and other pharmacotherapeutic agents. The area of plasma levels has not been

well researched and needs more investigation before routine assessment of methadone (or LAAM) blood levels can be recommended as a definite guide to dosing.

Dosage adjustment is always guided by outcomes criteria, which include

- Cessation of withdrawal symptoms
- Cessation of illicit opioid use (as measured by negative urines) and reduction of drug-seeking behavior
- Establishment of a blockade dosage (that is, a methadone dosage that blocks the euphoric effects of opioids and prevents desired sensations when heroin is injected)
- Absence of problematic craving (as measured by subjective report and clinical observations)
- Absence of signs and symptoms of too large a methadone dose.

A patient's optimal methadone dosage sometimes changes over time; patients should be informed at the outset of treatment that their dosage levels may need to be adjusted up or down periodically. Variations in dosage are a normal part of treatment and should not be considered a sign of treatment failure.

Recommendations About Dosage

The previous discussion illustrates the importance of establishing individualized dosage levels and the problems associated with a standardized-ceiling approach to treatment. Dosage levels vary among programs and individual patients. However, despite the support for higher doses in the treatment outcomes literature, considerable debate remains about dosage levels, especially about giving patients too much methadone. A rigid approach to dosing levels is inappropriate, inconsistent with the goals of substitution therapy, and contrary to findings of almost every treatment outcomes study that has examined this issue ([Cooper, 1992](#)).

These recommendations may result from a fear that it will be more difficult for patients to detoxify and enter a period of sustained remission free of substitution therapy if their methadone dosage level is too high. In fact, this fear appears to be without basis; there is no evidence that higher doses prevent patients from eventually becoming medication free. For example, one study found that those maintained on higher doses (80 mg a day) were more likely to become drug free than those on lower doses ([McGlothlin and Anglin, 1981a](#)). To further complicate this situation, some States have set inappropriately low (for example, 40, 60, or 80 mg) limits on the maximum methadone dosage. These limits are not articulated in FDA regulations, which recommend a ceiling of 100 mg and permit dosages of more than 100 mg with clinical justification.

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There is some concern in the treatment field that, without upper dosage limits, patients will manipulate the system to obtain higher dosages. Manipulative behavior is common among

addicts, and treatment program personnel should be able to distinguish requests that reflect drug-seeking behavior from those that reflect a desire to obtain more control over illicit substance use. Thus, the panel makes the following recommendations:

- Programs should use flexible dosing strategies
- Routine use of low dosages (less than 40 mg a day of methadone) should be discouraged
- The average dosage should be in the range of 60 to 100 mg of methadone a day (or its LAAM equivalent)
- Programs should be allowed to increase dosages to reflect the needs of patients, up to or even over 120 mg.

For some patients, a dosage in the lower end of the range will be sufficient. When adjusting dosages upward, gradual increases (10 mg per week) will reduce the chances of stimulating drug-seeking behavior because patients will become tolerant to euphoric drug effects fairly quickly. Thus, the concern that raising the dosage will stimulate drug-seeking behavior can be greatly reduced by slow dosage increments.

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Conditions That May Effect Dose Levels

Medical conditions, medications, and other conditions (for example, pregnancy) affect the establishment and maintenance of adequate methadone (and LAAM) dosage levels. The previous *TIP State Methadone Treatment Guidelines* provides a detailed discussion of these issues.

Other factors have implications for determining an adequate methadone dose. For example, the purity of heroin available to addicted patients varies. In many urban areas, the available heroin is more potent and cheaper than heroin sold elsewhere. Thus, the amount of heroin a patient reports using daily (reported in bags or spoons of heroin) is not always a reliable indicator of the actual amount of drug being ingested. A patient who reports using a relatively small amount may need higher doses to eliminate withdrawal and craving and to produce an appropriate blockade dose if purity is high. In addition, because of individual differences in metabolism, some patients who report using large amounts of heroin can be stabilized on a lower dosage of methadone, while other patients who are using small amounts of heroin may have higher tolerance to opioids.

Therefore, assumptions about heroin use are not adequate to establish an effective methadone or LAAM dosage. Also, patients increasingly report a return to intranasal heroin use. This change in the route of administration is in part due to increased purity, but is also related to concerns about needle use and fears of HIV transmission from shared drug paraphernalia. These issues have an enormous -- but unquantifiable -- impact on establishing an adequate dosage level of methadone.

It has been well established how important an adequate dosage is to the outcome of opioid substitution therapy. Although many programs are aware of these issues, managed care providers and purchasers of addiction treatment need to be educated about the relationship of adequate dosing to positive treatment outcomes.

Provision of Services

Drug counseling, administering urine tests, dispensing methadone, and other core elements of treatment should be provided onsite. However, programs vary in the degree to which treatments for associated problems can be provided. Although it is not always feasible to provide more specialized services onsite, they are of growing importance for patients in methadone treatment and should be considered a program goal, particularly for treating significant health problems such as serious psychiatric problems (for example, schizophrenia and major depression), TB, HIV, and sexually transmitted diseases (STDs).

Patient compliance with treatment often drops dramatically when services are provided through offsite referral. In one study, patients in a methadone program were offered onsite or offsite medical services. Of those offered onsite services, 92 percent received them, while only 35 percent of those referred offsite received the services ([Umbricht-Schneider et al., 1994](#)). Even when referrals are made to services in close proximity to the methadone clinic, noncompliance can be significant. This problem can be especially important in TB prophylaxis, where medication noncompliance can have serious public health consequences.

A special situation applies to programs that receive set-aside funds for serving pregnant women and women with dependent children. These programs are required by Federal regulations issued in 1993 (45 C.F.R. Part 96) to provide or arrange for primary medical care, including

- Prenatal care and childcare during substance abuse treatment
- Primary pediatric care for patients' children, including immunizations
- Gender-specific substance abuse treatment and other therapeutic interventions (for example, to address issues such as relationships, sexual and physical abuse, parenting, and childcare)
- Therapeutic interventions for children
- Case management for the above services.

These regulations are described more fully in the TIP *State Methadone Treatment Guidelines*.

In addition, States are urged to require all programs that serve women to provide

- Case management

- Employment and training programs
 - Education and special education programs
 - Drug-free housing for women and their children
 - Prenatal care and other health services
 - Therapeutic day care for children, Head Start, and other early childhood programs.
-

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Cultural issues are very important in delivering effective services and making patients feel accepted by the program. For example, a program in a Latino neighborhood with few Spanish-speaking staff members is very likely to be perceived as culturally insensitive and to be less acceptable and effective. The cultural experiences of many African Americans are very different from those of white Americans, and programs that do not attempt to understand these issues or to develop staff empathy toward them will most likely be at a similar disadvantage. All of these issues are especially important considerations for matching strategies.

Monitoring the Delivery of Services

Simply offering services does not mean that patients will receive them. Thus, mechanisms are needed to ensure that patients receive services, both on- and offsite. The case management model that utilizes the patient's primary counselor is appropriate to use in tracking the receipt of services. The case manager maintains contacts with staff within the treatment program and staff from outside agencies involved in the patient's care. Documentation and recordkeeping are key activities of case management. Standards of documentation and regulatory requirements guide programs in this area.

A comprehensive treatment plan process can also be effective in monitoring service delivery. This approach requires that clinicians and patients set specific goals and measure progress toward achieving these goals within a review period. It also may be appropriate to utilize a global treatment planning model when a single system is delivering a multimodality approach. Under this approach, if a patient requires opioid substitution therapy as well as services from a specialty partial hospitalization program and from a nonhospital rehabilitation program, the treatment plan should include these other modalities. This inclusion facilitates coordination of care and guides therapeutic efforts. It also allows for the verification of service delivery.

Treatment Elements

Assessment and Continuing Evaluation

As described in [Chapter 2](#), the process of assessing patients for associated problems, developing treatment plans that match patient needs to specific interventions, and integrating these interventions into the overall treatment program forms one of the key aspects of patient-treatment matching within opioid substitution therapy. The assessment forms the basis for matching patients to a range of services. For example, psychotherapy and pharmacotherapy for psychiatric disorders, treatment of HIV and TB, vocational or job counseling, family therapy, legal assistance, and assistance with housing and shelter may need to be provided while the patient continues to receive the core elements of opioid substitution therapy. Participation in self-help groups is usually encouraged as well; some programs have provided space and time so that these groups can meet during clinic hours.

Once a patient has been assessed, a treatment plan is developed in collaboration with the patient. The treatment plan outlines short-term goals (for example, referral to a shelter for adequate housing) and long-term goals (for example, individual, group, or independent living, or engagement of the patient's family in treatment). The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requires both short- and long-term goals to be documented in the treatment plan; progress toward them must be measurable. Goal setting should also include a means and a time frame for achieving the goals. Ongoing monitoring should be carried out to ensure that services are received, interventions are working, new problems are identified, and services are adjusted accordingly when problems are resolved.

Among the components of ongoing assessment are review of urine test results, observations based upon patient contact, and review of patient compliance with the treatment plan.

Urine Testing

Urine testing is a vital element of assessment and treatment. It is a tool used to

- Determine patients progress and status in the program
- Determine when patients can move from an acute to a less acute phase of treatment ([see Chapter 3](#))
- Select patients who are allowed to have take-home medications
- Monitor methadone use and intervene in the diversion of take-home medication
- Reveal other substance use problems (for example, use of cocaine or benzodiazepines)
- Determine additional patient treatment needs.

Another TIP in this series, *State Methadone Treatment Guidelines*, has a separate chapter with detailed discussions of urine screening techniques and methods and of Federal regulations governing these procedures. A brief overview is provided here.

The first urine test is especially important since it is part of the initial evaluation. As noted in the FDA regulations, the presence of opioids in the urine does not establish a diagnosis of opioid

dependence, and the absence of opioids does not mean that current dependence does not exist. Thus, the clinical examination and medical history are the keys for determining the appropriateness of opioid substitution therapy. Nevertheless, the admitting urine test is an important piece of data, and it is critical that the sample, as well as other appropriate laboratory tests, be returned from a laboratory in a timely manner. Ideally, throughout the course of treatment, urine tests should be conducted more often rather than less often: at least once a week during the acute phase is recommended. Testing provides initial information for making timely decisions about treatment. It is also an important part of ongoing assessment and planning for continued treatment.

Programs often decrease testing dramatically after the acute phase of treatment because of lack of resources. Programs often operate on budgets that place extreme pressure on the feasibility of doing regular (at least weekly) urine testing. However, the panel strongly recommends that testing be done regularly to the extent possible and that programs continue to pursue funds for urine testing from their funding agencies.

To avoid deception, urines should be collected only under controlled conditions. The best situation is one in which urine specimens can be obtained through direct observation of the patients. Taking the temperature of the specimen immediately after collection is another means that many programs have found to be a reasonably reliable method for assuring compliance. The urine temperature should never be higher than body temperature, and it should not be more than 2 degrees below it. Some programs gauge urine temperature simply by feeling the specimen container by hand. It is important to acknowledge that false positives and negatives occur; thus, if a patient is adamant that a positive result is incorrect, additional specimens should be tested. A laboratory can occasionally make mistakes, but repeated mistakes, especially on samples from the same patient, are highly unlikely.

Patients' refusal to give urine samples is one of the many problems encountered in urine testing. Some patients refuse because they have used illicit drugs and they want to avoid losing privileges (take-home methadone) or are concerned that the program will report their drug use to the probation agency or child protective services. Some patients refuse urines because they have trouble urinating in front of a monitor.

Some strategies are helpful in addressing the issue of refusal. Offering patients water or coffee and asking them to wait for their methadone dose until they can urinate is sometimes helpful. Asking patients to return to the clinic later in the day is another strategy. The policy in some programs is to automatically consider a refusal as an indication of drug use. Regardless of the response, it is important for clinic staff to talk with patients about their concerns about urine testing. To make the appropriate intervention, staff must take the time to understand the problem from the patient's point of view. Many programs do not dispense the daily methadone dose until the scheduled urine sample is obtained, although exceptions are usually permitted in unusual circumstances. Other programs may dispense the medication but require the patient to return later in the day for urine testing. Recently, hair analysis has become available, and it is used by some clinics as a tool to obtain a 90-day drug use picture. However, it is expensive and its use and reliability are in the process of being thoroughly investigated and verified. In the future, if

the test is made more economical, hair analysis may constitute a state-of-the art monitoring system.

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Neuropsychological Testing

Patients seeking opioid substitution therapy often have cognitive deficits, such as problems in understanding or remembering. These deficits are typically of mild to moderate severity and attributable to the pharmacological effects of abused substances. They generally clear over a period of days to months if abstinence is sustained. Neuropsychological problems that persist warrant formal neurological testing to diagnose the type and severity of the problem and to guide treatment. Such testing is performed by trained professionals, either psychologists or physicians, and such services should be available to the program.

A few patients have severe cognitive deficits that interfere with compliance and other aspects of therapy. Staff should be trained to recognize the needs of these patients. They typically have extensive histories of dependence on alcohol, benzodiazepines, or other sedative drugs; advanced HIV infection; or a history of traumatic head injuries or cerebrovascular accidents. Such patients have difficulty assimilating information unless it is slowly presented and frequently repeated. They may fail at treatment unless special approaches are used. In addition, they are very likely to have difficulty with compliance if they are required to take medications for accompanying medical or psychiatric conditions. In such cases, dispensing the other medications along with the daily dose of methadone will greatly increase the chances of appropriate levels of compliance.

Patients with cognitive impairments often have difficulty assimilating information unless it is slowly presented and frequently repeated. They may fail at treatment unless special approaches are used.

Some patients may have difficulty reading or comprehending written information such as program rules or consent forms because of educational deficits or language difficulties. Such patients can usually be identified by careful observation during intake when they are reading and filling out forms. In most cases, staff can read the information to the patient and ask whether he or she understands it.

Medical Services

Patients entering opioid substitution therapy programs may have one or several comorbid medical conditions. As described in [Chapter 2](#), these conditions include

- HIV/AIDS
- TB
- Hepatitis
- Cirrhosis
- Syphilis and other STDs
- Chronic obstructive pulmonary disease
- Cardiomyopathy and heart disease
- Diabetes
- Hypertension
- Cellulitis.

All of these problems can be treated within the context of the opioid substitution therapy program if assessment is thorough and resources are available, or provisions are made through liaisons with the appropriate specialists. The integration of medical treatment for these and other comorbid conditions presents a major challenge and opportunity for matching strategies and a potentially cost-effective intervention for managed care.

Since associated medical problems may resolve or emerge, programs should establish protocols to screen and evaluate acute problems and to perform periodic reassessments. Periodic routine screenings should be conducted for hepatitis A, B, and C, syphilis, other STDs, TB, and HIV. Liver and kidney function should be routinely evaluated. All of these tests except that for HIV can be done as part of a routine evaluation; HIV testing requires written permission from the patient, along with pre- and posttest counseling. Some programs repeat physical examinations annually, others every 2 years. The panel recommends performing periodic physical examinations no less often than every 2 years and performing tuberculin skin tests every 6 to 12 months.

Administration of medication and treatment is best conducted onsite to observe patient compliance. Onsite services are particularly important for patients who need TB treatment, because they are far less likely to comply with offsite treatment. As discussed above, a recent study by [Umbricht-Schneiter and associates \(1994\)](#) found that compliance with medical care was significantly better when services were provided onsite.

The panel recommends performing periodic physical examinations no less often than every 2 years and performing tuberculin skin tests every 6 to 12 months.

If onsite services are not feasible, it is important to develop strong linkages with appropriate resources, and to monitor patient compliance on a regular basis. This can be done by the

counselor, by an NP or PA, or by assigning a staff member to coordinate and to follow up on all referrals to offsite providers.

Psychiatric Services

Patients with untreated substance use and psychiatric disorders do poorly in treatment and often drop out of methadone programs. Thus, it is critical that programs address substance use and psychiatric disorders. It is not appropriate or desirable to withhold methadone treatment from patients with these disorders. The best strategy is to attempt to stabilize the patient's addiction and use appropriate treatments to address AOD disorders and psychiatric problems.

The abuse of cocaine by patients in opioid substitution therapy is a growing problem. A recent report estimated that up to 75 percent of patients in substitution therapy might be abusing cocaine ([Avants et al., 1994](#)). Currently, there are no substitution therapies for treating cocaine or sedative dependence. However, a wide range of behavioral and psychosocial treatment interventions have demonstrated efficacy in reducing or eliminating use of these drugs. They include talking therapies, such as individual and group counseling and psychotherapy, and self-help groups. Most of these strategies have been developed and studied in drug-free rehabilitation programs. Manuals to facilitate implementation are available ([Raison et al., 1989](#); [Washton, 1992](#)). In addition, Mercer and associates as well as Mercer and Woody have written unpublished manuals ([1994](#)) which are also available.

Much less work has been done on systematically developing and evaluating psychosocial treatments for substance use disorders among methadone or LAAM patients. However, treatment outcomes studies have demonstrated significant reductions in cocaine and other drug use among methadone-maintained persons as a consequence of drug counseling and the other psychosocial services ([Arndt et. al., 1992](#); [McLellan et al, 1993](#); [Kosten et al., 1992](#); [Magura et al., 1991](#)). These reductions are not as great as those seen for heroin and opioids; however, they are clinically significant and support the value of delivering good drug counseling and other services along with the substitution medication.

Patients with nicotine addiction should be strongly encouraged to quit, especially those who are motivated to do so. Programs should consider offering educational sessions on smoking cessation.

Pharmacological Treatments

Although methadone and LAAM have some antianxiety effects and weak antipsychotic effects, opioid substitution therapy has limited efficacy in addressing these conditions and, in fact, was never intended for this purpose. However, a variety of pharmacological treatments have proven effective in treating these and other psychiatric disorders, and should be used when indicated. Another TIP in this series, *Assessment and Treatment of Patients With Coexisting Mental Illness and Alcohol and Other Drug Abuse*, has a separate chapter addressing pharmacologic management of patients with dual diagnoses. (Nonpharmacological treatments -- counseling and psychotherapy -- are discussed in a separate section later in this chapter.)

Useful medications include antipsychotics, lithium, and antidepressants. Benzodiazepines are widely used to treat anxiety disorders, but they present special problems with this population because of their widespread abuse. As a result, there is a common belief that benzodiazepines are contraindicated in methadone patients; however, there are no studies that confirm this belief. A large number of studies indicate major differences in the abuse liability among benzodiazepines. Those having a rapid onset of action (alprazolam and diazepam) appear to have significantly higher abuse liability than drugs of the same class having a slower onset, such as oxazepam (Serax). Since these drugs have a very wide margin of safety and are effective in reducing anxiety even when used over extended periods of time, the use of benzodiazepines with a low abuse liability for selected patients may be helpful and is worthy of further study. In fact, there are several case reports in which benzodiazepines, particularly those with very low abuse liability, have been used with success among selected patients with substance use disorders ([Adinoff, 1992](#); [American Psychiatric Association, 1990](#); [Griffiths et al., 1984](#); [Sellers et al., 1993](#)).

The nonbenzodiazepine buspirone (BuSpar) has none of the sedative effects of benzodiazepines and thus its abuse potential is essentially nonexistent. It has a slower onset of action than other antianxiety drugs, which may account for its low rate of use. It has some antidepressant effects. Investigative clinicians continue to learn more about the effects of this medication, which has a complex profile and may affect a multitude of symptoms. Tricyclic antidepressants have been used with some success to treat anxiety disorders in this population.

Acupuncture

Acupuncture may provide some symptom relief for patients having difficulty managing anxiety, or it may be used as an adjunct to outpatient detoxification from benzodiazepines or alcohol. Acupuncture is the use of thin needles inserted subcutaneously at points on the body believed to be related to organs in need of stimulation. Electro-acupuncture applies small amounts of electricity to needles or staples at body points believed to affect opioid withdrawal. The use of acupuncture for the treatment of opioid withdrawal was first reported by Wen and Cheung in 1973. Its efficacy has been questioned by many ("[Acupuncture: the Position Paper of the National Council Against Fraud](#)," 1991; [Alling et al., 1990](#); [Ter Reit et al., 1990](#); [Whitehead, 1978](#)).

Although research on acupuncture in the treatment of opioid withdrawal is limited, it appears to be somewhat effective in reducing both objective withdrawal and subjective discomfort. Acupuncture may be helpful during withdrawal as an adjunctive treatment to the psychosocial approach. It may be a helpful alternative to alleviate withdrawal discomfort for opioid substitution therapy patients who seek outpatient, nonpharmacological treatment alternatives for cocaine dependence or for low levels of benzodiazepine dependence. More research is needed to determine what techniques are helpful, how acupuncture works, and how it relates to more traditional interventions ([Kleber, 1994](#)).

Counseling, Behavioral Treatments, and Psychotherapy

An important element of substitution therapy is providing support to patients through counseling. Studies on the efficacy of methadone treatment have shown that programs that provide regular, frequent, structured, drug-focused counseling realize better outcomes than programs that provide little or no counseling ([Ball and Ross, 1991](#); [McLellan et al., 1993](#)). Patient counseling can be provided individually or in group sessions. Special counseling groups for patients' families and significant others often help to engage the patients' support system in the recovery process. Intensive outpatient treatment is one approach to counseling and psychotherapy that has proved effective with substance abuse populations. A separate TIP in this series, *Intensive Outpatient Treatment for Alcohol and Other Drug Abuse*, describes this level of care.

More research is needed to determine what acupuncture techniques are helpful, how acupuncture works, and how it relates to more traditional interventions.

Specialized counseling on topics such as general healthcare, exercise, nutrition, and HIV/AIDS can also be offered. Behavioral treatments, such as contingency contracting, have been found to be especially effective in opioid substitution therapy; patients often are allowed take-home methadone based on continued "clean" urine samples. For some patients, specialized psychotherapy often helps to address some of the emotional and behavioral problems that interfere with treatment progress (Woody, et al., [1983](#); [1984](#)). These treatment modalities are described in the following sections.

Some patients may resist counseling, psychotherapy, and other forms of treatment because they are not ready for change. These patients may have entered methadone treatment not because of a desire to stop using drugs but because they are concerned about other aspects of their lives or their physical health; others may be ordered into treatment by the courts. Strategies for engaging these patients more fully in the treatment process are described in [Chapter 3](#).

Studies on the efficacy of methadone treatment have shown that programs that provide regular, frequent, structured drug-focused counseling realize better outcomes than do programs that provide little or no counseling.

As described above, many patients in opioid substitution therapy programs have mild or moderate cognitive impairments resulting from chronic alcohol and other drug abuse or from brain damage due to injuries. Many have poor reading skills or are illiterate. Counseling and psychotherapy should take these deficits into account. Psychoeducational materials should be

designed and presented in a way that allows all patients to comprehend and internalize the content.

Individual and Group Counseling

The major focus of counseling is to provide support and guidance, especially to stop AOD use; to monitor problematic behaviors; to help the patient comply with clinic rules; and to offer referrals to medical, social, and legal services. Counseling provides support for a drug-free lifestyle and encourages abstinence from AODs. The Center for Substance Abuse Treatment (CSAT) has recently published *Treatment of Opiate Addiction With Methadone: A Counselor Manual*. This manual facilitates the training of new counselors and improves the quality of the counseling component in methadone treatment.

In individual counseling, the patient meets with a counselor periodically, from once a month to several times a week. Some patients in the acute phase of treatment meet with a counselor daily. The frequency of sessions varies according to the patient's condition, the phase of treatment, and sometimes the State's provisions. In some States, Medicaid regulations and contracts may require or limit services for methadone patients regardless of their needs or treatment phase.

The counselor providing services

- Reviews urinalysis reports
- Encourages the patient to talk about important personal or family issues
- Helps the patient resolve acute social or personal crises
- Encourages the patient to seek and maintain gainful employment
- Provides liaison services with physicians, courts, and social service agencies
- Encourages the patient to discuss problem areas, such as ongoing health and financial problems
- Arranges for changes in methadone dosage or take-home medication
- Helps the patient comply with program rules and policies.

Counselors also help patients with problems in other areas, such as dealing with the criminal justice system or arranging transportation to obtain medical services.

Standard components of AOD counseling include

- Motivation enhancement
- Education about addiction and the effects of AODs
- Education about relapse prevention strategies, such as how to avoid or best respond to "people, places, and things" that trigger drug craving
- Identification of special unexpected problems
- Assistance in compliance with program rules and regulations
- Stress and time management techniques
- Assistance in structuring waking time and setting up schedules
- Assistance in developing a healthy lifestyle involving exercise, good nutrition, smoking cessation, and avoidance of risky sexual practices

- Assistance in becoming involved in socially productive activities such as community organizations, church groups, or self-help groups such as Narcotics Anonymous (NA) or Methadone Anonymous (MA).

A typical counseling session might include the following activities:

- Reviewing results of urine tests
- Reviewing the treatment plan
- Identifying measurable goals and time frames
- Reviewing the patient's progress in achieving the treatment goals, including abstinence and abstinence-related behaviors
- Discussing legal and family problems, such as reporting to probation officers or complying with safety contracts that were implemented as a result of abuse of family members
- Reviewing emergencies and how to address them.

When the primary counselor serves as case manager, he or she provides a liaison with other services. Medical staff should discuss a patient's medical problems with his or her counselor so that the counselor can help the patient understand the importance of complying with medical treatment and keeping appointments. In turn, the counselor should convey to medical staff any observations about the patient's medical condition.

Although counselors are not expected to understand medical treatments, pathophysiology, or pharmacotherapy in the same way that a medically trained professional does, they should have some general knowledge of common medical conditions and their treatment. This knowledge enables counselors to work more closely and effectively with medical and psychiatric staff in developing matching strategies that combine medical, psychiatric, and drug-focused treatments.

The type, frequency, and duration of group counseling sessions vary significantly by program. Some groups keep the same membership and stay together for a limited time; others are more long term and may involve a "rolling" membership. Some groups are psychoeducational, with a curriculum including workbooks and homework assignments. Formats or topics for each session are designed to provide a strong structure, using models that have been adapted from those used in drug-free rehabilitation programs.

- Common psychoeducational group counseling topics include
- Drug education and drug cessation (including focused lectures on these topics)
- Dynamics of addiction
- Medical effects of certain drugs
- Medical impairments
- Impact of drug use on families
- Introduction to self-help groups such as NA.

Other topics designed to provide a strong structure may include

- Leisure activities
- Interpersonal relationships
- Drinking and driving

- Building self-esteem
- Dynamics of relapse
- Medications
- Psychiatric illnesses
- Side effects of methadone
- Skill-building and relapse prevention
- Stress management and relaxation
- Assertiveness training
- Communication skills training
- Time management
- HIV/AIDS
- Nutrition and exercise
- Smoking cessation
- Parenting groups
- Other compulsive behaviors.

Ideally, groups should be led by individuals trained in group therapy. Most State agencies offer basic training courses in group process and group dynamics. Group counseling sessions are often directed by following guidelines in a manual. Use of a manual allows different staff to lead particular groups and permits programs flexibility in running groups; it also ensures that all groups cover standard information. Manuals for use in opioid substitution therapy are not as common as those for drug-free programs. However, the same principles can easily be adapted to methadone patients. The necessary step is to emphasize the need to take the prescribed pharmacotherapy, but no other substances.

Some groups, such as process-oriented groups, are not compatible with use of a manual, but are highly effective in helping patients change their attitudes and behaviors. For example, some patients are resistant to group therapy and refuse to attend. Offering small process groups specifically geared toward these patient's concerns and needs allows the therapist to explore the patients' resistance to groups and past group therapy experiences and to address fears of talking in a group setting. In forming groups, programs should also consider mixed groups -- for example, men and women and stable and unstable patients. Such groups are often more beneficial than extremely homogeneous groups.

Parenting Groups

Many patients who enter opioid substitution therapy programs have children. Many have lost custody of their children (either temporarily or permanently) because of substance abuse and addiction problems. Concerns about children and parenting can be an important focus of treatment. For some, these concerns are the motivating factor that brings them into treatment. Developing groups for patients who are concerned about their parenting skills can be very valuable in engaging them in the recovery process.

Groups may be educational and address specific topics, including information about Child Protection Services, resource availability, day care services, breastfeeding and methadone, and so forth. Skill-building groups for parents often address limit setting and appropriate discipline; divorce, visitation, and parenting; and dealing with a sick child. Psychodynamic groups for

parents help patients explore issues such as ambivalence about losing a child, fear of parenting, and coping with anger, shame, and guilt. Programs should ask patients what their needs are in these areas and develop groups accordingly.

Family Counseling

Family interventions can be done in an individual or group format. They are generally of two types: counseling interventions and family therapy. The interventions are discussed in the section on psychotherapy. Family counseling consists of one or more sessions that includes educational information and gives participants the opportunity to ventilate feelings and describe problems. Some families have very negative attitudes about substitution therapy and need considerable education about its benefits. In these groups, family members learn about the treatment program and how to support the efforts of the patient and staff to treat the dependence and associated problems. This type of intervention can usually be done by counseling staff, sometimes with the brief assistance of a psychiatric social worker or psychiatrist.

Concerns about children and parenting can be an important focus of treatment. For some patients, these concerns are the motivating factor that brings them into treatment. Developing groups for patients who are concerned about their parenting skills can be very valuable in engaging them in the recovery process.

Some programs have a monthly "family night" or some other forum for ongoing family involvement. In these settings, all family members of patients are invited to an informal gathering to discuss their concerns or questions about the program or their relative's progress. This ongoing format can be very helpful in providing family support for therapy, and for identifying acute family problems that need more focused treatment.

In deciding whether a family requires psychotherapy for more serious, multigenerational problems that might be helped by a family approach to drug use, a good evaluation is essential. One approach is to have a psychiatric social worker who has been trained in family therapy, or a person who specializes in family therapy interview every new patient as part of the initial evaluation. Information obtained at this interview, often supplemented with information obtained during the acute phase of treatment, can then be used to determine if family therapy is indicated.

Other Types of Counseling

In addition to drug-focused counseling and family therapy, specialized, highly focused counseling is available for several issues, including

- Relapse prevention, often combined with time management strategies
- Sexually transmitted diseases and responsible sexual behavior

- Vocational counseling (sometimes linked with cognitive testing and conducted in collaboration with vocational agencies)
- Smoking cessation
- Nutrition (a dietician or nurse discusses nutrition, including special needs of HIV-infected persons)
- Exercise, including aerobic types of exercise and
- meditative exercise such as yoga (a dietician or nurse can facilitate discussion)
- HIV pre- and posttest counseling
- Support groups.

The last two issues are especially important and are discussed in more detail below.

HIV Counseling

Counseling about preventing HIV infection, including safer sexual behaviors, needle sharing, and other risky behavior associated with drug use, should be a routine component of opioid substitution therapy programs. Specialized HIV counseling should be provided before and after a patient receives an HIV antibody test. In addition, patients with HIV infection may receive specialized counseling about their disease, treatment options, and participation in clinical trials if they are available and if the patient is interested.

Pretest HIV counseling tends to be factual and medically based. Posttest counseling for persons who test negative primarily addresses risk reduction. Persons with positive results need counseling about the meaning of the test, how to cope with problems and issues raised by the results, the availability of support groups for HIV-infected persons, and instruction on behaviors that will prevent them from infecting others. Linking the HIV-positive person with medical and other services is an important part of posttest counseling.

There are several ways to conduct individual and group counseling about reducing HIV risk and to conduct pre- and posttest counseling. The program can develop consultative relationships with outside testers. However, onsite counseling is the preferred approach. Partner support groups are a useful component of HIV counseling. They offer patients who test HIV positive and their partners opportunities to learn safer sex behaviors and cope with the disease.

Support Groups

Patients are encouraged to attend community groups that support the efforts of the treatment program. Such groups include Alcoholics Anonymous (AA), Narcotics Anonymous, and Cocaine Anonymous (CA). Because NA has a drug-free orientation, many patients on methadone resist attending for fear of being criticized. This problem has led to the emergence of Methadone Anonymous groups. In addition, groups for persons who have a psychiatric disorder and a substance use disorder -- often called "double-trouble" groups -- are also increasingly available. None of these groups is a professional treatment group; however, they have been shown to be effective in helping people remain abstinent and they can be an important augmentation to therapy.

Some families have very negative attitudes about substitution therapy and need considerable education about its benefits. In family counseling groups, family members learn about the treatment program and how to support the efforts of the patient and staff to treat the dependence and its associated problems.

Any of these support groups can be held on- or offsite. Providers are encouraged to seek out the local leadership of the group and request that groups be conducted onsite. This arrangement allows patients to benefit from the philosophy of a group such as NA in a setting that is safe and with participants of similar background. The frequency of attendance at self-help groups should be determined by the patient and treatment staff. Some self-help groups provide onsite childcare, which facilitates attendance. Treatment staff should be familiar with a range of local groups, their schedules, and their childcare services.

Because Narcotics Anonymous has a drug-free orientation, many patients on methadone resist attending for fear of being criticized. This problem has led to the emergence of Methadone Anonymous groups.

Behavioral Treatments

Behavioral treatments are derived from the principles of learning and behavior change developed by psychologists and behavioral scientists. AOD abuse and dependence are seen as involving major elements of learning and as being influenced by many aspects of the patient's environment and circumstances. Many elements of this behavioral view and of behavioral treatments are now widely accepted and routinely incorporated into substance abuse education and counseling. For example, the emphasis on identifying high-risk circumstances that increase the likelihood of AOD use and of developing alternative coping responses to those circumstances is derived from a behavioral approach, as is the emphasis on developing personally rewarding activities as alternatives to AOD abuse and related activities.

Another aspect of behavioral treatment that can be beneficial in conjunction with methadone treatment is the use of behavioral incentives or contingencies to motivate and reward therapeutically appropriate behaviors. Incentives may be provided and may be effective in increasing a wide variety of desirable outcomes: maintaining negative urine specimens, attending counseling sessions, keeping medical appointments, and working or volunteering. One of the most effective rewards available in methadone clinics is the medication take-home privilege. Other potential incentives or rewards include increasing or decreasing counseling services, scheduling administration of methadone at specific and more desirable times of day, and facilitating access to goods or services such as meal vouchers, gift certificates, entertainment tickets, and toys for patients' children. Designing such incentive or reward programs may require significant effort but it can add an important dimension to a treatment program.

An important principle of behavioral treatment is that positive incentives or rewards for desirable behavior are more effective than negative or punishing consequences or threats for undesirable behavior. This is a critically important principle, and one that is often difficult for treatment staff to learn and implement. Negative or punishing consequences tend to have the undesirable effect of driving patients out of treatment rather than retaining them and encouraging as much improvement as attainable. To be most effective, behavioral treatment contingencies should be clearly spelled out and reliably and consistently implemented. Contingencies can be either individualized for patients based on specific areas of behavior change or implemented on a uniform, program-wide basis. Either strategy is acceptable. The efficacy of behavioral incentive treatments has been demonstrated in several well-designed studies ([Boudin, 1972](#); [Daley and Marlatt, 1992](#); [Melin et al., 1976](#); [Stitzer et al., 1992](#)). Such treatments are especially effective when medication take-home privileges have been made contingent upon providing drug-free urine samples.

When patients are being considered for administrative termination from treatment because of nonresponse, it may be especially worthwhile to spell out to patients a specific set of behavioral contingencies that can lead to their retention in treatment. For example, a patient who consistently fails to attend prescribed counseling sessions might be informed that a gradual detoxification will be initiated but that it will be terminated and the patient's dose gradually restored contingent upon attending the prescribed sessions.

Psychotherapy

The term *psychotherapy* is often used synonymously with counseling but it has a significantly different focus. While drug counseling focuses mainly on external events and processes, psychotherapy aims to identify and modify intrapsychic processes that contribute to the substance use disorder and interfere with treatment progress. Psychotherapy is most often used to treat patients whose psychiatric distress interferes with their ability to participate in routine treatment. Because of the instability of many patients in the acute phase of treatment, methadone patients usually begin psychotherapy late in the acute phases or after entering the rehabilitation phase. In the methadone treatment context, psychotherapy tends to be more time limited than counseling. Psychotherapy is often combined with pharmacotherapy and counseling.

While drug counseling focuses mainly on external events and processes, psychotherapy aims to identify and modify intrapsychic processes that contribute to the substance use disorder and interfere with treatment progress.

Psychotherapy was originally developed to treat nonpsychotic psychiatric disorders such as anxiety and depression. It has been used with persons who have substance use disorders and has been found effective for psychiatrically impaired patients in substitution therapy programs, but only when combined with substitution therapy and drug counseling (Woody et al., [1983](#); [1984](#); [in press](#)).

There are many schools of psychotherapy, and several methods have been used in opioid substitution programs. Among these are cognitive-behavioral psychotherapy, supportive-expressive psychotherapy, and interpersonal psychotherapy. It is beyond the scope of this TIP to describe these psychotherapies in detail; however, it should be noted that they have been most successfully used with patients who have significant levels of nonpsychotic psychiatric symptoms. These patients are sometimes described in the literature as being "high severity," and they typically do not respond well to the drug-focused counseling available in methadone programs. Several authors have described effective psychotherapeutic approaches to these patients ([Luborsky et al., 1994](#); [Beck et al., 1993](#)).

Individual and Group Psychotherapy

Psychotherapies constitute a set of specific interventions that typically require higher level training. Individual psychotherapy usually is provided once or twice a week in sessions lasting about 1 hour. Staff responsible for psychotherapy generally have more specialized training than those who are responsible for drug-focused counseling. They typically possess graduate degrees and receive supervised training in the modality they will be employing, most often through a clinical internship.

Group psychotherapy is effective for many patients. Psychotherapy groups may have advantages over individual therapy, not only because of their cost-effectiveness, but also because many patients benefit significantly from group support. However, some patients with severe symptoms cannot participate in the group process. Some may have problems or issues that require confidential treatment.

Issues related to gender or sexuality can also be important in the choice of individual or group therapy. Some women may feel uncomfortable in the typically male-dominated substance abuse treatment program; others feel embarrassed about very personal issues related to their addiction. In such cases, individual therapy or women-only therapy groups are often very helpful.

Specialized psychotherapies have been developed to address specific issues that are increasingly common among patients in substitution therapy. They include therapies involving sexual issues, such as incest. A history of sexual abuse is more common among injection drug users, especially women, than in the general population. Psychiatric symptoms, substance use, and relapse among successfully treated patients may be related to unresolved issues related to a history of sexual abuse. Sexual histories, including questions about rape, incest, and childhood abuse, should be part of the assessment. Specialized training in dealing with these issues is strongly recommended for psychotherapists who treat these patients. The American Association of Sex Educators, Counselors, and Therapists provides training and certification in this area and is a resource that may be useful in obtaining training.

Some patients may make use of psychodynamic, process-oriented groups that are less structured, with a focus on interpersonal relationship building, insight, reflection, and discussion. These groups require careful selection of patients who are ready and able to make a long-term commitment to this process. As mentioned above, group treatment can provide patients with a sense that they are not alone in dealing with problems, even very serious ones. Such

"normalization" is often a first step toward new coping strategies. In the group, patients can also learn coping skills and receive support from others.

Family Therapy

Involvement of the family in treatment is helpful for many patients. The family can provide strong support for the patient's recovery. Family therapy, which is a more intensive involvement, is best reserved for families that have very serious and ongoing problems, generally involving behaviors or attitudes that contribute to the maintenance of the addiction. These families are often termed "dysfunctional" and can sometimes benefit from long-term therapy that is delivered by highly trained therapists. Family therapy often addresses adverse issues that arise over two or three generations. Because many patients are reluctant to discuss family issues during the acute phase of treatment, family therapy is usually reserved until the beginning of the rehabilitation phase of treatment.

Family therapy is best reserved for families that have very serious and ongoing problems, generally involving behaviors or attitudes that contribute to the maintenance of the addiction. Family therapy often addresses adverse issues that arise over two or three generations.

In conducting family therapy, families should be broadly defined as individuals who are significant in the patient's life. Nontraditional families include significant others, gay and lesbian partners, friends of homeless persons, and shelter staff. Family therapy is a specialized service and should be provided by individuals with special training. Because many methadone treatment programs do not provide family therapy, referrals to community-based services are often needed.

Special Considerations in Providing Treatment

Spirituality

Spirituality refers to an involvement in socially desirable activities or processes that are beyond the immediate details of daily life and personal self-interest. Ethical behavior, consideration for the interests of others, community involvement, helping others, and participating in organized religion are all ways in which spirituality can be expressed. Persons who recover from substance use disorders often experience an increased interest in the spiritual aspects of their lives, and addressing a person's spirituality is widely recognized as an important aspect of recovery. For example, assessment of spirituality is required by the Joint Commission on Accreditation of Healthcare Organizations, and the development of that aspect of one's personal life is encouraged by most self-help groups.

Approaching patients in relation to their spirituality can also provide an opportunity for the patient to connect or reconnect with community and family. This process can begin with the initial assessment which helps establish the patient's cultural context. For example, if a patient

who was raised in a church-going family has not attended church in a long time, there may be a need to address underlying issues about that individual's adjustment in the community. Psychosocial treatment could involve persuading the individual to return to church as part the process of reconnecting with the community and family, gaining acceptance, and forgiving himself or herself.

Children

Lack of adequate childcare is a barrier for many single working parents in substitution therapy programs. For example, some patients report missing clinic dosing hours or scheduled counseling appointments because they have no one to watch their children. Some bring their children to the clinic and into counseling sessions; this alternative makes it difficult for the patient and counselor to have the privacy and concentration to have productive sessions. Some may arrange for another patient to watch their children while they attend counseling, but this is not always practical, available, or desirable.

Ideally, waiting rooms should be able to accommodate children. However, some programs lack physical space and are not safe for children because they do not have a separate or secure room with adult supervision (for times when patients are with staff in treatment sessions). Lead paint and asbestos often found in many urban facilities may pose another hazard to children. Programs without space must require patients to have immediate control of their children so that they do not disrupt treatment. Some programs prohibit children in the facility out of concern that their presence poses a danger to them or a distraction to patients' focus on recovery. Some programs allow patients to bring their children to the facility early in treatment so that childcare concerns will not interfere with treatment.

Childcare services available onsite that allow patients to leave their children in a supervised environment are ideal. Structured childcare services provide an opportunity for observation, assessment, and problem identification, which can be valuable in planning a patient's treatment program. Childcare services are strongly recommended for the relatively small subgroup of substitution therapy programs that provide outpatient hospital treatment.

Many programs have limited resources, and childcare services are currently available in very few programs. Developing arrangements for childcare is a challenging -- but not impossible -- task. A program may develop a collaborative project with an area college or university that has a child development program. The program can provide the space and a coordinating staff member, while the college could provide students who need child assessment experience and supervision. Another alternative would be for two or more service providers to jointly develop a childcare program or negotiate a contract with a childcare facility. The proposed Federal block grant regulations on set-aside services for women will probably increase support for programs to institute childcare services and should stimulate their development.

Many programs have limited resources, and onsite childcare services are currently available in very few programs. Developing arrangements for childcare is a challenging -- but not impossible -- task.

Although childcare services clearly benefit patients, programs must be careful when considering taking on childcare responsibilities because of issues related to licensing and insurance. Staff should not be expected to provide childcare services unless they are specially equipped to do so.

Access for the Disabled

Increasingly, methadone treatment facilities are faced with developing ways to address the needs of disabled patients. Many patients with AIDS have disabilities such as blindness or are sometimes not strong enough to visit the clinic. Other patients have hearing impairments or other physical handicaps.

At the very least, programs should be well maintained and barrier free. Programs should be aware of measures necessary to comply with the Americans With Disabilities Act. They should provide wheel chair accessibility, handicapped-accessible bathrooms, access for patients with seeing-eye dogs, Telecommunications Device for the Deaf (TDD) machines, and sign language services. If services are not available onsite, provisions should be made through contracted agreements and used on an as-needed basis.

Because of the growing number of patients who are unable to visit the clinic daily as a result of disabilities, home dosing with methadone has become an increasing need. Although many patients can be provided with take-home medication, not all patients are eligible. For example, some patients with AIDS or other medical problems that affect neurological functioning are unable to manage their medication without supervision. Other medically compromised patients may continue to use illicit drugs or abuse alcohol and are ineligible for take-home dosing. These patients pose major dilemmas for opioid substitution programs and treating them requires creative planning.

Solutions vary from program to program and in different geographic areas. For those who do not meet take-home eligibility criteria, home dosing can be negotiated under the Federal regulations emergency dosing provisions. For example, some programs identify a responsible family member or significant support person to assist in the dosing process. With the patient's permission, these individuals are educated about methadone and are responsible for picking up the methadone from the program, ensuring safe storage (for example, locked boxes and limited key access), and administering the medication daily. For patients who cannot identify such a person, programs may negotiate services through the Visiting Nurses Association or comparable programs to assist in this process.

Some programs deliver the medication directly to the patient's home. This delivery may be impractical for programs that serve patients who live a great distance from the clinic and is costly for programs that do not have adequate staff. Switching from methadone to LAAM can also be considered in these cases because the long-acting nature of LAAM allows patients to visit the clinic for dosing every other day rather than daily.

Regardless of the strategy, meeting the needs of homebound patients is a challenge for all involved. This service can be time consuming and expensive, and it can introduce safety and security dilemmas. Consideration may be given to negotiations with pharmacies or interested physicians who could work directly with a licensed narcotics treatment program to propose solutions for home dosing in geographically inaccessible areas. Programs are encouraged to engage in discussions with their State agencies, the DEA, and Federal and local FDA agencies to assist in developing creative solutions.

Nonfraternization Between Patients And Staff

Programs must establish clear standards barring outside engagement between program personnel and patients, including prohibitions on dates and intimate or financial involvement of any kind. Patients not infrequently offer to sell goods or services to program staff. Staff should not be patients' sponsors in 12-step programs, although it is acceptable if they meet at 12-step meetings. If staff fraternize with patients in these ways, the boundaries necessary to provide effective medical and clinical services will be compromised, and the treatment process will probably be negatively affected.

Programs need to establish clear standards barring outside engagement between program personnel and patients, including prohibitions on dates and intimate or financial involvement of any kind. Otherwise, the boundaries necessary to provide effective clinical services will be compromised.

Noncompliance

Repeated skipping of methadone doses should be an indicator of a problem situation. Reasons for missed doses include incarceration, hospitalization, changed work schedules, or transportation difficulties. Programs should establish a certain number of missed days per month (for example, 3 missed days) as indicative of a treatment problem. Programs can approach such situations by mobilizing staff to identify problems and determine a response. Rarely should patients be administratively discharged simply for missing appointments.

Although some patients may be eager to receive counseling and other psychosocial services, patients generally request admission to a methadone program in order to receive methadone. They may not want other services, at least at the time they apply for treatment. If methadone were not available, many opioid-dependent persons would not seek help or be receptive to receiving it. However, regular counseling appointments have been shown to be associated with significantly improved treatment outcomes ([McLellan, et al., 1993](#)). Thus, the program should expect and even demand participation in an appropriate level of psychosocial treatment. This level should be determined by the patient's clinical status. Some severely impaired patients may require several hours per week of care, while others will require considerably less.

Certain treatment issues, especially those that relate to public health, should not be negotiated with patients. For example, testing and treatment for TB should be required because of its contagious nature. Although HIV can be transmitted to others, stipulating that patients must be tested for HIV may drive opioid users away from treatment because they fear the consequences of learning that they are HIV positive.

Conclusions and Recommendations

Patients receiving opioid substitution therapy should receive a core program that provides structure, support, and assistance for the numerous problems that often accompany addiction. Substitution therapy should begin with a comprehensive biopsychosocial assessment, including a physical examination and appropriate laboratory tests, including a drug screen. The core addiction treatment services should include drug counseling, regular urine testing, and use of both programmatic and individual behavioral interventions designed to suppress substance use and encourage socially productive behaviors. Treatment plans should be implemented, reviewed, and modified at appropriate intervals depending on the needs of the patient.

The problems that patients often have because of addiction can be very complex and difficult to treat. They range from acute situational problems, such as brief depressive episodes or family crises that spontaneously resolve or need only brief interventions, to chronic and life-threatening problems, such as HIV disease or schizophrenia, that need long-term, medically sophisticated treatment. The intensity and nature of these problems will change, requiring alterations in the treatment plan.

If untreated, these associated problems usually have a negative influence on the course of treatment. Adequate treatment of associated problems requires having staff available, either onsite or through referral or liaisons with other facilities, who have training in the areas to be addressed. Treatment for the addiction must be coordinated with that of the associated problems.

The combination of comprehensive assessment, addiction-focused treatment, and therapy or intervention for associated problems is one of the major strategies for matching patients to treatment. Research studies have shown that treating the addiction along with the associated problems will significantly improve the outcomes achieved with opioid substitution therapy. The availability and appropriate use of a wide range of treatment elements are key aspects of patient-treatment matching strategies.

The program should expect and even demand participation in an appropriate level of psychosocial treatment. This level should be determined by the patient's clinical status.

Summary

The recommendations made in this chapter are summarized below.

Core Services

1. A core group of services is essential for administering opioid substitution therapy, including
 - Assessing patients
 - Dispensing medication
 - Administering urine tests
 - Identifying acute medical or psychiatric and neuropsychological problems when they occur
 - Counseling
 - Evaluating and addressing family problems
 - Referring patients to additional services as needed
 - Performing clerical functions and keeping records
 - Providing security.

Staff

1. Programs should establish careful screening procedures during job interviews to ensure that individuals with biases or rigid ideas about treatment are not hired.
2. Programs should hire staff who are flexible, educated, self-disciplined, and willing to learn, and who get along with a multidisciplinary group.

Dosing

1. Programs should use flexible dosing strategies.
2. Routine use of low dosages (less than 40 mg a day of methadone) should be discouraged.
3. The average dosage for programs should be in the range of 60 to 100 mg of methadone a day (or its LAAM equivalent).
4. Programs should be allowed to increase dosages to reflect the needs of patients, up to or more than 120 mg.
5. Patients should be informed at the outset of treatment that their dosage levels may need to be adjusted up or down periodically. Variations in dosage are a normal part of treatment and should not be considered a sign of treatment failure.

Other Services

1. Programs should establish monitoring mechanisms to ensure that patients receive services for medical, psychiatric, and other problems, both on- and offsite.
2. Given the prevalence of medical comorbidities and their impact on patients, periodic routine screenings for various medical conditions are indicated, including
 - Hepatitis A, B, and C
 - Syphilis and other sexually transmitted diseases
 - Tuberculosis
 - Liver and kidney function
 - HIV testing.
3. Periodic physical examinations should be performed no less often than every 2 years, and tuberculin skin tests every 6 to 12 months.

4. Onsite services for TB treatment are particularly important for patients because they are far less likely to comply with offsite treatment.
5. If onsite services are not feasible, it is important to develop strong linkages with appropriate resources and to monitor patient compliance on a regular basis.
6. It is critical that programs address substance use and psychiatric disorders. It is not appropriate or desirable to withhold methadone treatment from patients with these disorders.
7. Programs should consider offering educational sessions on smoking cessation.
8. Patients should be encouraged to attend community self-help and other groups that support the efforts of the treatment program.
9. Treatment staff should be familiar with a range of local self-help and support groups, their schedules, and their childcare services.

Counseling, Behavioral Treatments, and Psychotherapy

1. To be most effective, behavioral treatment contingencies should be clearly spelled out and reliably and consistently implemented.
2. Psychotherapists who treat patients with a history of sexual abuse should have specialized training in dealing with these issues.
3. In conducting family therapy, families should be broadly defined as individuals who are significant in the patient's life.

Other Issues in Providing Care

1. Childcare services are strongly recommended for the relatively small subgroup of substitution therapy programs that provide day hospital treatment.
2. A methadone treatment facility should be well maintained and barrier free for disabled persons.
3. Programs should establish clear standards with program personnel that bar outside engagement with patients. This prohibition includes dates, intimate involvement, and financial involvement of any kind.
4. Staff should not be patient sponsors in 12-step programs, although it is acceptable if they meet at 12-step meetings.
5. The program should expect and even demand participation in an appropriate level of psychosocial treatment. This level should be determined by the patient's clinical status.
6. Programs should establish a certain number of missed days per month (for example, 3 missed days) as indicative of a treatment problem.

Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series

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Chapter 5 -- Self-Monitoring and Evaluation

Self-monitoring and evaluation are ways of gaining dynamic, reliable, and up-to-date information about patient and program characteristics and the frequency and efficacy of services delivered. This information is necessary to accurately describe patient flow and service delivery patterns and to examine outcomes. Self-monitoring and evaluation need not be complicated or excessively time consuming. They do not require extensive resources.

This chapter is directed not to evaluators and researchers but to personnel working in the alcohol and other drug (AOD) treatment field who are interested in applying evaluative tools to their work and moving their programs toward increased self-monitoring and evaluation.

In the following pages, the concepts underlying effective self-monitoring and evaluation are explained. A step-by-step guide to evaluation is provided, which explains how and why each step should be followed. Examples make it clear how these processes are pertinent to this Treatment Improvement Protocol (TIP) subject -- matching patients to type and intensity of opioid substitution therapy services. Instruments are suggested, and a detailed hypothetical example is presented within the framework that has been outlined. The example demonstrates not only how an agency can monitor itself on one specific issue (the effectiveness of treating methadone patients with a high level of psychopathology is the example used), but also how it can use the information gained from this study to make changes in its program, and how the effect of those changes can then be evaluated.

A very basic introduction to the concepts of monitoring and evaluation is outlined here. To understand the distinctions among these various concepts, it is helpful to look at a continuum of evaluative efforts and what their aims are. Those wishing a more advanced approach are directed to other sources, and to another TIP, entitled *Developing State Outcomes Monitoring Systems for Alcohol and Other Drug Abuse Treatment*. It provides more detailed discussions of the principles and goals of outcomes monitoring and their importance in the current healthcare environment. The National Institute of Drug Abuse (NIDA) has developed a valuable package, entitled *How Good Is Your Drug Abuse Treatment Program?* ([National Institute on Drug Abuse, 1993](#)), which provides practical guidelines.

Other useful sources include a number of publications that report the outcomes or results of research studies on AOD abuse treatment ([Ball and Ross, 1991](#); [Hubbard et al, 1989](#); [Pickens et al, 1991](#); [Rounsaville et al, 1993](#); [Simpson and Sells, 1982](#); and [Tims and Ludford, 1984](#)). Full reference citations are provided in the Bibliography, Appendix A.

Self-Monitoring

Self-monitoring, the first point on the continuum, is something a program does to help itself. It is generally perceived as more modest in goals and execution than self-evaluation or evaluation done by an external source. Self-monitoring usually refers to the selection and regular inspection of intermediate indicators of patient outcomes (which, it is hoped, are predictive of final outcomes).

Self-monitoring employs tools that are nontechnical and easy to use. It utilizes a program's internal resources to collect and analyze information in a focused area. It incorporates some kind of feedback system. Optimally, self-monitoring is a continuous part of a program's operation, with periodic assessment of results and action taken in response to findings.

Program Evaluation

Program evaluation is a more elaborate form of monitoring than self-monitoring, using a more formal methodology. It may be done by internal or external evaluators. Its objective is also quality improvement.

Evaluation can be done by the State, by a reimbursor, by an independent evaluator, or by a program itself. Evaluation does not have to be an overly ambitious, expensive, or daunting prospect. It need not be elaborate. It does not have to include all the elements of an academic research evaluation project, which tests a hypothesis. Rather, it can be a specific, focused effort to determine whether a program, or part of a program, is meeting specific goals and objectives.

Evaluation can begin with the basic formulation of a few questions and can then look for ways to answer them. It can cover a broad range of activities, but persons wanting to evaluate their program need not be overwhelmed by looking at the full range. A program can keep it simple, beginning with a small component to evaluate, then selecting and choosing the questions that -- when answered -- will provide the most useful information. Any well-conceived effort, no matter how limited, can contribute to better understanding of treatment practices.

Evaluation need not be elaborate. It can be a specific, focused effort to determine whether a program, or part of a program, is meeting specific goals and objectives.

Why Evaluate?

Evaluation is an important and necessary part of the operation of any opioid substitution therapy program. It gathers information that is useful and based on measurable data collected by the scientific method, rather than on intuition and impression.

Self-monitoring and evaluation serve to meet patients' needs. Both approaches study active elements of treatment. By measuring treatment progress and outcomes, self-monitoring and evaluation can improve the process of patient matching. They can help identify populations that need specific services and can evaluate the effectiveness of such services once they are implemented. They can support program and policy changes and can document the effects of changes on policies and procedures. They can help with decisions about cost-effectiveness and suggest new ways of looking at programs. The application of these uses will be illustrated in the hypothetical example at the end of this chapter.

Regulatory requirements, and questions that arise from them, can serve as triggers to suggest specific self-monitoring and evaluation needs. In this era of managed care and limited funding, it is increasingly important to implement a program of self-monitoring and evaluation. Such a program should be part of an organization's quality improvement strategy and its accountability to regulators and to the public. Some external agencies, including reimbursers, seek the demonstration of effectiveness that evaluation can provide. Evaluation can help programs satisfy regulatory requirements and document compliance with regulations and standards.

Evaluation can be useful at any point in programming, certainly not only at patient discharge. This point is particularly pertinent to the long-term, continuing nature of much of methadone treatment. Periodic behavioral change, not just final outcomes, can be measured by evaluation.

Most studies collect baseline data and then establish an endpoint that is either the point of discharge or a point at a specified time after the beginning of treatment. Such approaches may provide some useful data. However, in a program where patients may not be discharged or may not complete treatment for a long time, it is also necessary to look at continual measures of change. This view may mean revising standard notions of outcomes evaluation, because there are no outcomes to study other than behavioral change within treatment. It is important to note that outcome does not necessarily imply finality, even when the patient leaves treatment.

The results of evaluation can feed directly back into treatment services. For example, once information has been gathered about baseline rates of drug use, staff and patients can set goals -- such as the goal of reducing positive urine tests to a certain level. As data are collected, they can be used to revise goals as necessary. The goals of evaluation vary greatly among programs. In setting treatment goals, tradeoffs have to be made between the intensity of service and the number of patients who can be served. The ideal situation is to provide services for all those who need them in as intensive an approach as necessary. However, achieving this goal is usually impossible in practice.

Evaluation also serves an important public education function. Despite the large body of literature demonstrating the efficacy of opioid substitution therapy, there remains much public skepticism about whether it works. Sometimes this skepticism is related to philosophical differences. For example, many people feel that addiction should be treated only in a drug-free environment. Skepticism may also be more experiential. Citizens reading in their local newspaper about drug trafficking in the proximity of a methadone clinic may jump to the unjustified conclusion that the program is not effective in treating opioid addiction. Thus, negative opinions are formed.

To the extent that self-monitoring and evaluation can demonstrate that opioid substitution therapy achieves its goals with a certain number of patients, they can perform a valuable role in public education. If a study showed, for example, that of the 200 people served by a methadone program more than 75 percent tested negative for illicit drug use a year after entering the program, the study would be a useful demonstration of program effectiveness that could be brought to the attention of local public officials and the media. Evaluations can be designed specifically to gather information to present to public officials, legislators, or State agencies to illustrate specific points.

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Goals of Evaluation

A primary goal of evaluation in the context of this TIP is to improve the process of matching patients to opioid substitution therapy services. In many programs, decisions about matching are often made intuitively. Evaluation can help to assess the impact of these decisions. It can provide both prospective and retrospective data to quantify the matching process and can identify patients needing additional or different services. Evaluation of the matching process can be valuable in the following areas:

- Phases of treatment
- Levels of care
- Types of services
- Identification of specific program elements
- Identification of subpopulations.

The public expects certain results from drug treatment in general, and methadone treatment specifically, including the cessation or reduction of illegal drug use, the reduction of crime, and improvement in patients' social functioning. Programs may also want to assess patient progress in treatment. Evaluation is one way to determine if public expectations are being met and how patients are progressing in treatment. In some cases expectations may be unrealistic, for example, that patients will stop all drug use, become abstinent after a certain period, or remain abstinent once they leave treatment. Evaluation results can provide a realistic picture of what can be expected from methadone treatment, as well as demonstrate the extent to which patients are meeting these expectations.

Although the task of establishing evaluation goals may sound straightforward in the context of opioid substitution therapy programs, it can be quite complex. Patient characteristics, program philosophy, and State licensing and reimbursement requirements can influence this process. For example, the duration of treatment may be prescribed by State policy. In some States, a course of

methadone treatment is limited to 2 years; others support much longer-term therapy that may continue for a dozen years or more. A program that has time-limited treatment and patient goals directed toward becoming medication free (methadone free) presents different issues than a program whose goals focus on achieving a change in lifestyle with the continued use of methadone (or another opioid substitute). Therefore, the goal of evaluation must be considered within the context of the goal of the opioid substitution program.

Evaluations can be used as mechanisms to influence policy change. Data collected can provide information for reimbursers, who may be inclined to limit treatment, contain costs, and make services available to more people. When establishing objectives and designing self-monitoring and evaluation projects, it is critical that these distinctions be understood and considered and that the goals be clearly established. This issue is discussed in greater detail in the section of this chapter on the role of program philosophy in evaluation.

To determine clear objectives, questions that should be asked include

- Is the program working as well as it should?
- How can it be improved?
- How does it compare with similar programs?
- Are patients being matched to appropriate treatments?
- How satisfied are patients with the services provided?
- What happens when changes are made?
- Can the program be more efficient and more cost-effective?

The Role of Program Philosophy in Evaluation

One of the sources of the variability discussed above is program philosophy. Program personnel sometimes do not use known results of research and evaluation to guide clinical practice because these results support the use of techniques that differ from those consistent with their own particular program philosophies. Very strong feelings and emotions are often involved, and the role of the evaluator is to remain neutral. The effect of program philosophy is one aspect that should be evaluated and considered.

Issues of program philosophy that must be considered include the following:

Short-term vs. long-term treatment. As discussed above, the length of treatment relates to the program's ultimate goal. Is the ultimate goal abstinence from any drug (including methadone), or is it a significant reduction of drug use within a long-term maintenance model?

Specific goals centered on HIV and AIDS. These goals can involve a number of areas -- perhaps most critically, the program's discharge policies. For example, since human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) is such an important factor in treating injection drug users, should patients be kept in treatment as long as possible with the expectation that this length of stay will reduce HIV transmission? This question has an increasingly important impact on evaluation, as well as on treatment decisions and the establishment of program goals. HIV has tipped the balance of the argument about the duration

of methadone treatment toward liberal retention policies. This factor has come to play an increasingly important role in program evaluation, particularly in jurisdictions with a high incidence of HIV infection.

Dosage levels. Dosage levels, which are discussed in greater detail in [Chapter 4](#), are frequently a matter of dispute and controversy. Determination of dosages may be based as much on philosophy as on clinical guidelines. This additional philosophical issue must be considered within the context of evaluation.

Various other program policies and practices may be influenced by philosophy. In different models, the same data can be interpreted in radically different ways. For example, consider a study comparing illicit drug use in a program based on an abstinence model and in a substantial-reduction, long-term maintenance-model program. In the abstinence program model-program, the finding that sporadic use occurs in 50 percent of the patients after 2 years of treatment could be interpreted by some to represent a substantial failure. However, in the long-term maintenance-model program, the reduction of drug use from 100 percent to sporadic use in 50 percent of the patients, with the other 50 percent being abstinent, would represent a major gain.

Outcomes and Process Evaluation

The evaluation of outcomes and of process are different, requiring different approaches. Both approaches should be considered since they answer different questions. Outcomes evaluation focuses on results; process evaluation focuses on how results were achieved and tends to identify the active ingredients of treatment. A subset of process evaluation is implementation analysis, which evaluates the success of an action that has been taken in response to the results of an evaluation.

Evaluations can be used as mechanisms to influence policy change. Data collected can provide information for reimbursers, who may be inclined to limit treatment, contain costs, and make services available to more people.

Outcomes Evaluation

Outcomes evaluation focuses on the patient and patient progress (or lack of progress) during and after participation in a program or some facet of a program. When looking at outcomes evaluation, terms such as "success" and "failure" should be avoided; rather, considerations of progress markers and behavioral improvements should be the guideposts. Even small improvements may be significant, and feedback can provide important reinforcement to the staff and encouragement to the patient. For example, a patient outcomes evaluation might measure drug use (as quantified by the results of urinalysis) in patients with high levels of psychopathology who are referred for mental health services. This example is discussed in detail at the end of this chapter.

Researchers measure a variety of variables to assess outcomes of treatment for opioid-addicted patients. These may include drug use, criminal activity, attitudes, vocational skills, employment, institutional adjustment, family relationships, and involvement in social activities. The particular measures chosen should include the behaviors specified in the goals and objectives of the programs. The evaluation of a treatment program designed to reduce substance use, decrease criminal involvement, improve self-concept, and increase job skills must collect data in each of these areas to determine whether the expected changes have taken place. Other areas can also be measured to assess the general impact of the program on patients' behaviors or on aspects of the larger community.

Outcomes evaluation can also measure and assess the impact of a program or an element of a program, and its ability to produce desired changes in the patients who are exposed to it. For example, a program might provide bus tokens to its patients to help them with transportation to and from services. After a certain period of time during which the bus tokens are provided, an evaluation might be conducted to determine whether program attendance has improved. This is an example of a simple evaluation for which only attendance data would need to be collected. The most reliable evaluation uses a control group for comparison (for example, a group of patients to whom bus tokens were not provided), but this is not always a practical approach for programs to take.

Researchers measure a variety of variables to assess outcomes of treatment for opiate-addicted patients. These may include drug use, criminal activity, attitudes, vocational skills, employment, institutional adjustment, family relationships, and involvement in social activities.

New programs provide an opportunity to build in continuous data collection mechanisms from the start. Programs may choose not to use the data, but evaluation should be built in. However, it is important not to begin evaluation too early when implementing a new program or part of a program. The program should become stabilized before evaluation begins.

Process evaluation. Process evaluation describes what is happening within the "black box" of the treatment program. "Black box," a commonly used term in this context, refers to the concept that patients go into a program as known and described entities and come out with certain measurable outcomes; but what actually goes on in the program -- or black box -- is not readily apparent. Process evaluation allows for successful replication of programs that are achieving their goals, because it looks at the factors that are responsible for this goal achievement.

By documenting what actually happens over the course of the intervention, a process evaluation can help interpret the results of outcomes evaluation. Also, either explicitly or implicitly, the results of a process evaluation provide an assessment of the strengths and weaknesses of a program and suggest ways in which the program can be improved, thereby serving as a management tool for program development. Finally, the documentation produced by a process

evaluation can be used to develop a manual describing the theory and practice of the treatment program, a helpful guide for others wishing to replicate the program.

Process evaluation has proved to be a useful tool for examining the procedures of a treatment program in comparison with its stated intent. Through a process evaluation, the evaluator can determine whether the subjects actually received an intervention as it was intended to be delivered. The evaluator can also measure the intensity and duration of the services received by the subjects.

Implementation analysis is a particular type of process evaluation that can be applied to new programs or new program elements. Implementation analysis should begin as early as possible in order to fully document the process. It is also useful, once an evaluation has disclosed that over time, as a result of something new, certain changes have been taking place -- for example, increased attendance at counseling sessions since the provision of bus tokens. Implementation analysis describes how the new program was implemented, considering what the steps were and who the players were. The analysis looks at such things as planning meetings (when they were held and who attended), specific problems and barriers that were encountered, strategies that were used to overcome problems and barriers, and modifications to the original plan that were necessary.

What Can We Learn From Previous Studies?

The benefits and problems of methadone treatment have been studied extensively. Much can be learned from the evaluation work that has already been done in this field, including what the greatest needs are for future evaluative work. Data have been collected to describe effects of opioid substitution therapy on reductions in injection drug use, other drug use, criminal activity, unemployment, and other areas. Instruments have been designed to collect these data. A body of literature focuses on medication levels, treatment program variation, and factors that are predictive of retention. Some of these studies are discussed in [Chapter 1](#) and in another TIP *State Methadone Treatment Guidelines*.

There are a number of good literature reviews of evaluations of methadone treatment ([Ball and Ross, 1991](#); [Cooper, 1992](#); [Hubbard et al, 1989](#); [Institute of Medicine, 1990b](#); [Simpson and Sells, 1982](#); [Simpson and Sells, 1990](#); [Tims et al., in press](#)).

The existing literature can inform the process of evaluation and program improvement. It can offer evaluators a sense of what is generally acceptable and examples of how other programs typically define success rates. The results of earlier evaluations can suggest ideas about how existing work can be applied or adapted to particular program needs and how it can guide current evaluative efforts.

There are large gaps, however, in existing work. Only a few studies have been done of the actual process of matching patients to services. A 1990 report from the General Accounting Office (GAO) found that none of the methadone maintenance programs studied "systematically evaluated their effectiveness in treating patients." Virtually none of the studies have used control

groups. Most studies have high dropout rates ([Simpson and Joe, 1993](#)). Results must be considered within the context of these limitations.

By documenting what happens over the course of the intervention, a process evaluation can help interpret the results of outcomes evaluation and can be used to develop a manual describing theory and practice of the treatment program.

Getting Ready to Evaluate

This section offers a general look at evaluation that can be related specifically to opioid substitution therapy programs and even more specifically to patient matching within these programs. The methodology that is used in individual studies depends on the purpose of the specific evaluation, but a number of general principles are applicable to any evaluation.

General Principles

Keep It Simple

The evaluation should not be overly ambitious. A poorly designed evaluation is likely to be worse than no evaluation at all. The best way of ensuring quality and achieving goals is to keep the project manageable. The less complex an evaluation project, the more likely it is to be well planned and implemented.

Use Evaluation as a Problem-Solving Tool

As discussed in the introduction to this chapter, evaluation can provide data for both internal and external use. Externally, data can be used to provide accountability. Internally, data can be a valuable agent for quality improvement. In the context of the philosophical problems that opioid substitution therapy programs may encounter and their need to explain their methods and goals, evaluation can help demonstrate program effectiveness.

Use Available Data Whenever Possible

Evaluation does not need to be a major undertaking that starts from scratch. Often data already available can be plugged in to answer the question being considered for evaluation. Use of available data is discussed in greater detail in the section of this chapter on the data collection process. One primary fact to remember in using previously collected data is that the data must be handled consistently and applied appropriately. In other words, apples shouldn't be compared with oranges.

Don't Work in Isolation

In designing and implementing self-monitoring and evaluation projects, it is desirable to include personnel involved in various aspects of programming whenever possible. Staff investment in and commitment to the study is critical for the success of the project. A number of different approaches can be considered.

One is creating a team. Team members can provide a range of expertise and opinions for the evaluation process, even if no members are actually specialists in evaluation. An evaluation team might include the members of the treatment team, including the program director, the medical director, counselors, nurses, and educators.

Another approach is to contract with an outside agency to perform the evaluation. Whether the evaluation is done internally or by an outside agency depends on several factors, including internal resources, available funding, and the purpose of the evaluation. If it is being done for internal information-gathering or quality improvement purposes, and program personnel are confident that the data collection procedure will provide reliable data, an in-house effort may be sufficient. However, independent (external) evaluations often have more credibility and may be necessary if an evaluation is being conducted, for example, to demonstrate effectiveness to payer sources, the State, or other regulators or interested parties.

Programs located in communities with universities can sometimes gain valuable help from faculty and doctoral students in designing and implementing research studies.

Domains

[Ball and Ross \(1991\)](#) describe four domains that must be considered in evaluating substance abuse treatment. By considering each of these four areas for data collection and study, the treatment process can be broadly conceptualized and insight can be gained into what actually occurs in treatment. Evaluation strategies may differ for each area, and these should be considered in a general way before designing an individual evaluation project. A common pitfall in designing evaluation studies is looking at only one domain. Once a broad overview is achieved, programs can select the variables that are most meaningful for their study, assigning primary or secondary values to them. Each domain is discussed briefly below.

Patients. Information gained from life histories and current health surveys of opioid-addicted patients has long been valued as a tool for treatment evaluation. Collection of these data has always been emphasized in substance abuse treatment, although the focus of treatment has changed somewhat through the years as addicted patients have been considered increasingly within medical and psychiatric contexts.

Programs. [Ball and Ross \(1991\)](#) describe the domain of the treatment program as "conspicuously neglected" in most substance abuse treatment evaluations. They list four program areas that should be considered:

- Setting or environment

- Policy
- Staff and leadership
- Physical facility and other resources.

Services. In looking at the actual provision of treatment and adjunct services, evaluators should consider

- Methadone dosage
- Clinic hours
- Number and type of counseling sessions
- Medical and psychiatric services
- Educational and vocational services
- Urine screening
- Any other services that are provided.

Outcomes. Common outcome criteria that have been studied include measures of drug use, criminality, treatment retention rates, and employment status. The study of outcomes is discussed further in the next section of this chapter.

Four general principles should be used in designing evaluations:

- Keep it simple.
 - Use evaluation as a problem-solving tool.
 - Use available data whenever possible.
 - Don't work in isolation.
-

Steps in Conducting an Evaluation

By answering the following eight questions in order, a step-by-step approach to evaluation will proceed in a logical, systematic fashion:

- What do you want to know?
- What data are needed to answer the question?
- What information is already available?
- Who or what will be studied?
- How will you collect the data?
- What are the results?
- What do the results mean?
- What is next?

What Do You Want To Know?

Determining exactly what you want to find out from your evaluation involves a number of steps in order to refine and focus the evaluation questions as much as possible:

- Arrive at a broad goal statement. Why do you want to know the answers to the questions you have posed? What is the goal of obtaining this information?
- Move from articulating the general goal statement to defining specific objectives. A general goal might be to improve patient outcomes. This goal must be narrowed to a specific, feasible project that can be measured through evaluation.
- Identify the question as either a process or outcome question. Examples of outcome questions are, "Will providing childcare reduce program dropouts among parenting women?" or "How effective is the program in treating patients with high levels of psychopathology, and how often are these patients referred for mental health services?" An example of a process question is, "What are the problems and barriers in providing mental health services for patients with a high level of psychopathology, and what strategies can be used to overcome these problems?"
- Look at what others have learned about this question through previous research. The National Clearinghouse for Alcohol and Drug Information (NCADI) is a useful resource for this purpose.

Determine the relevance of previous research to your specific evaluation project. What you find in existing research may help further define your evaluation questions and identify instruments that may be used to collect data.

As previously described, questions about methadone therapy have been answered in a number of studies through the years. For example, it is well documented that the longer patients stay in treatment, the better they do; likewise, the more services they receive, the better patient outcomes will be. Instead of attempting to look at these broad questions that have already been answered, most evaluators would do well to focus their studies more narrowly and look, for example, at questions such as

- How can patients be retained in the program for the first 90 days (the period critical to their becoming engaged in treatment)?
- What are the reasons given for dropping out of treatment?
- What is the range of services that patients receive?
- How does the program use the results of urine screens?

What Data Are Needed To Answer the Question?

Some factors that will help determine what data are needed include whether the evaluation being done is a process or outcomes evaluation, which domains are being covered, and whether an implementation analysis is involved.

Define the Categories of Data

The data that are collected should be directly relevant to the question and should consider all domains appropriate to the question. When considering how well patient matching procedures work, the approach should consider both program and patient variables. As [Ball and Ross \(1991\)](#)

have pointed out, there is often a tendency to look only at patient data when evaluating. But it is important to consider the other areas that are appropriate to the question, such as program setting, services, staffing, and so forth.

Select Specific Variables

The specific variables about which data will be collected will depend on the question. Variables may be quite diverse and may include patient, program, and outcome variables. For example, patient variables may include gender and ethnicity; program variables may include staffing ratio, number of scheduled counseling appointments, and dosage levels; and outcome variables may include rates of positive urine tests, patient satisfaction, and compliance with scheduled counseling appointments.

A word of caution about variables: If the number of variables under consideration for a planned evaluation seems to be approaching an unmanageable level, it is likely that the project is overly ambitious. This is a clue to reconsider and reduce the scope of the original question.

What Information Is Already Available?

Next, it must be specifically determined what data are already available that pertain to the selected variables. What relevant information is already in program records? What existing data are available elsewhere, where and in what form, and how can these data be abstracted? What, if any, are the barriers to obtaining it? Are there confidentiality issues that affect extracting and collecting data? Are existing data in a form that can be used for comparative purposes with the data that will be obtained from this evaluation? One possible starting point may be to establish a uniform data set, if this does not already exist. A program may standardize assessment forms or instruments as well as indicators of ongoing progress.

When possible, data to be used in evaluations should be computerized. Computerization creates a database that can be used in subsequent projects, and provides a format for quantifying information for the current project.

Existing resources may include

- Program data (for example, patient records, results of urine testing, and administrative and fiscal information)
 - The National Drug and Alcohol Treatment Unit Survey (NDATUS)
 - Client data system
 - State uniform data sets (if available)
 - Community social indicators
 - Census data
 - Health indicators
 - Crime data.
-

Patient variables may include gender and ethnicity; program variables may include staffing ratio, number of scheduled counseling appointments, and dosage levels; and outcome variables may include rates of positive urine tests, patient satisfaction, and compliance with scheduled counseling appointments.

Who or What Will Be Studied?

The next step is to identify the population or process that is to be evaluated. This identification depends on the evaluation question. For example, does the evaluation concern new patients coming into a program and how they will be matched to treatment? Or is it a look at outreach to a critical population such as addicted persons who are human immunodeficiency virus (HIV) positive, pregnant women, polydrug abusers, or people with disabilities? Or is it limited to assessing how existing patients are being matched to new or different services?

It may be a "what" rather than a "who" that is being evaluated. In the case of a State evaluation, the "whats" may be programs or elements of programs -- for example, program procedures such as intake or patient matching; program elements such as specific interventions, staff ratios, and characteristics; administrative procedures such as payer mix or dollar costs; or patient movement through phases of treatment.

After these determinations have been made, it is then possible to decide on the sampling strategy. Factors influencing this strategy include the scope of the research question, the resources, and the size of a program. A study of a small program may include everyone in a program. In other evaluations, for a number of reasons such as resources and manageability of the data, it may be necessary to sample only a portion of the population to be studied. If an evaluation is being conducted at the program level, the best procedure may be to sample among programs.

Sampling strategies also depend on the problem to be studied. For example, in a study focused on the program's success in administering purified protein derivative (PPD) skin tests for tuberculosis (TB) or on completing a physical examination on admissions, every patient admitted over a specified period of time might be sampled. On the other hand, if the study is focused on evaluating the frequency of opioid- or cocaine-positive urines, a random sample of persons who have been in the program for less than 6 months might be compared with a random sample of those who have been in the program for more than 2 years. Or, the rate of positive urines in the sample of newer patients could be compared with the overall rate of positive urines in the entire clinic.

It should be determined whether the evaluation will require approval by an institutional review board concerned with protection of human subjects and if patient consent is necessary. Care must be taken to ensure that consent is truly informed; the fact that patients are dependent on the opioid substitution services might give program staff undue influence over patients. This influence should not be abused in the evaluative process. Also, confidentiality must be ensured whether data are stored in a computer or in a paper file. Any other relevant ethical issues must also be considered.

It should be determined whether the evaluation will require approval by an institutional review board concerned with protection of human subjects.

How Do You Collect Data?

Selecting or Designing an Instrument

Data must be collected in an empirical, quantitative form. The first step in data collection is the identification or development of an instrument to be used for this purpose. The program may already collect data in a form that is amenable to the evaluation project, such as the results of urine tests or attendance records.

The development of a data collection instrument involves several steps. It is necessary to devise data fields, draw up a draft of the instrument, pilot test it, and then revise it based on results of the pilot study. Although this sounds complex -- and is, in some cases -- it can also be quite simple. The instrument may be just a single sheet with a few boxes on it. Piloting the instrument may simply involve a counselor's asking questions of a few patients. This procedure does not need to be a daunting, complicated process.

Certain guidelines must be followed so that the information collected is congruent with other existing resources. This is part of the challenge of putting together an instrument, and one of the reasons that all but the most experienced evaluators should probably use (or adapt) existing instruments. For example, if the instrument is to include an ethnicity category, it is necessary to be aware of the various ways to categorize ethnicity. Another example is drug use categories. An instrument may use the term narcotic to refer to opioids; another may use legal definitions and include cocaine or even marijuana under the narcotic category. Some consider alcohol a sedative-hypnotic drug, and others consider alcohol in a separate category. If questions are developed, categories should be parallel to those used in other data sources, so that collected data will be comparable with the other data.

A program developing a complex data-collection instrument should use the services of evaluation experts and consultants whenever possible. Many existing instruments may be applicable. For example, the Addiction Severity Index (ASI) or sections of the ASI may be useful. Several existing personality inventories may also be useful. Serious consideration should be given to using existing instruments, or portions of them, if they are appropriate. Sometimes only a few modifications are necessary to adapt an instrument to a program's particular evaluative purpose. Adapting an instrument is usually much easier than trying to invent a new tool.

A wide variety of such instruments is available. NIDA publishes a comprehensive list of existing instruments in the Diagnostic Source Book on Drug Abuse Research and Treatment ([Rounsaville et al., 1993](#)). Another useful guide is the DATAR Forms Manual: Instruments Used for Data Collection ([Simpson, 1992](#)). DATAR is the Drug Abuse Treatment for AIDS-Risk Reduction

project, which included an extensive evaluation component. The project is reviewed in a recent article by Simpson and associates ([Simpson et al., 1995](#)).

Serious consideration should be given to using existing instruments, or portions of them, if they are appropriate. Adapting an instrument is usually much easier than trying to invent a new tool.

Frequency and Duration of Data Collection

Part of designing an evaluation includes deciding with what frequency and over what duration of time data will be collected. If data are to be collected more than once, it is possible that more than one instrument will be necessary. These questions relate to whether the evaluation is a one-time look, or a survey of changes over time. If it is a one-time look, these questions are not applicable.

Staff Training

Training staff members to perform self-monitoring and evaluation does not have to be extensive or complicated. However, for data to be useful, a certain amount of training and staff support is necessary to standardize procedures and assure quality. Data must be collected using standardized methods in a way that protects its integrity. A written protocol explaining exactly how data should be collected is usually the best way for staff to understand the procedures to be used. Although all staff must participate, it is often best to assign responsibility for collecting data to one or two staff members.

Another purpose of training is to address concerns of staff members about the use of the results of the evaluation. There are no "right" or "wrong" results of evaluation. However, program personnel know that certain findings may reflect poorly on a program and may even jeopardize funding or accreditation. Staff members must be taught to use results -- whatever they may be -- in a proactive way, bringing problems out into the open and addressing them. Evaluation presents an opportunity for a program to move in a positive direction, perhaps seeking outside help from State technical assistance services. Programs that incorporate self-monitoring and evaluation information into a plan for improvement will be looked upon positively by the State, by regulators, and by reimbursers.

It is also important that procedures be developed to address specific points when conducting an evaluation. Interviewing is one area that often must be addressed. When interviewing patients is part of the evaluation process, procedures for interviewing should be prescribed. To some extent, the structure of the interview will be determined by the instrument used. Data collected in the interview should be quantifiable, and staff should receive training in conducting the interview in a way that will elicit data that can be quantified.

The interview site is another important consideration. The decision of whether to conduct interviews in a waiting room or in a private office, for example, could influence the way that

patients respond to questions. Another issue to consider is how to record or account for patients who refuse to be interviewed. Also, if the work involves abstracting information from existing patient records, it must be determined when this work can best be done so that records are still available for staff to use for routine purposes.

When all the data are gathered, standardized procedures are used to code, to enter, and to store data. These procedures require staff training and monitoring to ensure consistency and quality. Ever-increasingly, this type of work is being performed on computers, and the use of a computer is necessary for a large or complex project. However, it is important to note that computers are not essential for small-scale self-monitoring and evaluation. For some evaluations, a simple checklist is all that is necessary. If you are doing a study of drop-out rates, for example, your data may consist of simple, hand-drawn line graphs.

Computers are not essential for small-scale self-monitoring and evaluation. For some evaluations, a simple checklist is all that is necessary.

What Are the Results?

The results are to be found in the data that have been collected through the evaluation project. If data have been accurately defined and collected, they should provide at least some answers to the questions originally posed.

For example, suppose a program wants 100 percent compliance with PPD skin testing for TB. Investigators review 20 consecutive intakes over a 2-month period and find that five persons did not receive a PPD skin test. Corrective action is taken, and the study is repeated in 3 months. Consider another example: The program wants to be certain that all patients with more than one opioid-positive urine test a month are receiving adequate methadone doses. Records are reviewed, and all patients who have been in the program for more than 6 months and who have had more than one opioid-positive urine a month are identified. The treatment plan of any patient in this group whose methadone dose is below 60 mg is reviewed by a physician, the counselor, and the treatment team, and appropriate adjustments are made.

A data analysis strategy determines how the data should be aggregated and presented. Generally, results are compiled in an understandable format, which can vary from a simple percentage, bar, or line graph to sophisticated presentations. Usually some kind of narrative summary accompanies the graphic display of the results. Means or percentages must also be generated to make the statistics meaningful.

What Do the Results Mean?

The process of understanding evaluation results should involve consultation with experts and discussion among program staff. Objectives that were described in designing the evaluation and

the interpretation of the statistical data are both factors in determining what the collected data mean and how the data will be used.

The first point to be determined is whether the results answer the question that the evaluation attempted to address. Results may be clear, but just as often they may not be. Even in well-designed and well-executed evaluations, results may be inconclusive, which should not be discouraging to evaluators. Such results may lead to additional questions.

The program may want to involve a staff member or outside consultant with experience in statistical interpretation to help with interpreting the results, particularly when they are not clearcut. The sensitivity, background, and experience of the evaluators who have collected the data and who prepare the presentation of the material will affect the interpretation and understanding of the results of an evaluation. Analysis can be a complex process. Even if results are clear, implications may be less apparent. Questions of statistical and clinical significance must be considered. Such considerations can be guided, in part, by comparisons to previous studies that have been conducted on the same or similar topics.

Again, most caveats about interpretation and implications apply primarily to the more difficult and ambitious evaluation projects. Evaluators should not be intimidated by possibilities that may seem daunting. Often results are clear and implications are obvious. For example, consider the hypothetical illustration of distributing free bus tokens in an attempt to decrease patient dropout rates in the acute phase of treatment. Baseline data show that before bus tokens were distributed, the dropout rate for patients in the first 2 months of treatment was 30 percent. After 3 months of tokens distribution, the dropout rate for patients in the first 2 months of treatment was 15 percent. The distribution of the bus tokens was the only change in the program. Without a control group, interpretation of findings cannot be absolute. But it is fairly obvious that the results of using bus tokens were encouraging, and it is a practice that the program would want to continue, if feasible.

If the dropout rate had gone from 30 percent to 25 percent, the results would have been less clear, and more subjective judgments would have been necessary about the value of the intervention. Sometimes other factors must also be considered. For example, suppose that the first 2-month period (before bus tokens were distributed) was an exceptionally rainy period, while the sun shone nearly every day after the token distribution began. It is possible that the weather may have had as much influence on program attendance as the distribution of bus tokens. Or suppose that another factor had been introduced in the same time period, such as child care for patients with young children. These are elements that must be weighed by evaluators and then factored into interpretation of the study. As well, decisions must be made about any action taken as a result of the study and the design of future evaluations.

The implications of a more complex study are explored in the section of this chapter outlining a hypothetical evaluation of the need for mental health services for methadone patients with a high level of psychopathology.

Even in well-designed and well-executed evaluations, results may be inconclusive, which should not be discouraging to evaluators. Such results may lead to additional questions.

What Is Next?

The final questions of the evaluative process are: How can the data be applied? How can the program be improved on the basis of this evaluation? Once it has been decided that evaluation results are valid, the results of evaluation provide program personnel with a foundation for taking their next step.

Programs are constantly making changes, and the purpose of self-monitoring and evaluation is to make these changes part of a more conscious and reflective process. When a change is contemplated, consideration should be given to what the result will be if that change is made. This is a basic purpose of evaluation -- make a change, look at what happens when the change is made, decide whether the results are sufficiently successful to continue, and, if so, institutionalize the change.

Perhaps the most important point is that evaluation results should not just be filed away but should be used in some manner. Some results will point to recommendations for change. In some cases, positive results can be used to publicize the accomplishments of a program. Other findings will indicate the need for further evaluation. Some evaluation results can serve as a basis for discussions with funders or can provide the foundation for funding applications.

Clearly, there are many different options to consider when deciding what steps should follow evaluation and self-monitoring and what kinds of changes should be made. A general rule is to begin with the least invasive intervention, which might be as simple as releasing the data. Other options might include establishing new policies, changing regulations, applying sanctions, or implementing certain educational requirements for staff.

Several examples illustrate the "What is next?" step. Suppose a program wants to find out whether there is a correlation between the amount of group counseling a patient receives and whether the patient stays in treatment. Once the data are gathered and analyzed, it becomes clear that increased numbers of group counseling sessions are correlated with retention in treatment. That information can provide the foundation for an education program to inform program directors of the findings and encourage programs to increase their group counseling sessions. From there, an implementation analysis (a form of process evaluation) can be conducted to determine if this intervention is actually having an impact on the amount of group counseling that is available in the various programs.

This hypothetical evaluation of counseling is an example of an evaluation in which the unit of analysis is the program, not the patient (in contrast to the bus tokens example). In studying programs, it is important to be aware of variables that may influence outcomes, such as the size and age of the program, staffing patterns, or other internal components.

Another example of how evaluation data might be used to move programs in a certain direction can be seen in the case of a study in a midwestern State that showed that when methadone dosages were above certain levels, rates of illicit drug use by patients were lower (as measured by urine screens) than were rates when lower methadone dosages were used. Knowing that average dosing levels were considerably lower than the cut-off rate in the study, State officials began a campaign to educate providers and policymakers that lower rates of illicit drug use were associated with higher methadone dosing levels. This campaign included distribution of articles explaining the study, as well as presentation of conferences and workshops for practitioners to further disseminate the information.

A Hypothetical Evaluation

A number of hypothetical examples have been referred to throughout the preceding discussion of self-monitoring and evaluation. The following example¹ is a more complex exercise. [Exhibit 5-1](#) shows the practical application of the eight steps of evaluation to a specific example of an inhouse evaluative project. Based on the results of the program then instituted, certain program changes are implemented for a period of time, and the effectiveness of the intervention is then evaluated, as shown in [Exhibit 5-2](#).

Based on the results of the first evaluation, this hypothetical program then instituted the following actions:

- Routine screening of all patients on admission and every 6 months, using the psychological status section of the ASI.
- Establishment of formal liaison with a local mental health agency to ensure rapid intake for methadone patient referrals.
- Assignment of case managers to monitor the followup to ensure that mental health assessment this and treatment actually occur.
- Six months after initiating these changes, the program conducted a second study to evaluate the effectiveness of the intervention.

Conclusion

Self-monitoring and evaluation are important components of any opioid substitution therapy program. Whether a program employs self-monitoring for regular self-inspection or uses evaluation to solve a problem or to gain a better look at the effects of change within a program, provisions for monitoring and evaluation are a necessity to programs concerned about patient-treatment matching. Self-monitoring and evaluation allow a program to engage in continuous quality improvement.

Designing and implementing an evaluation component need not be extensive or complex. In fact, simple and manageable projects that address the interests of a specific program are generally more successful than projects that are overly ambitious. Evaluation can be used to identify service needs, assess the effectiveness of services, support program and policy changes, document the effects of procedural changes, assist in decisions about cost-effectiveness, and provide information for public education. Regardless of the program's area of interest, consider a

systematic, step-by-step approach when designing the project. Include the four basic domains -- patients, programs, services, and outcomes -- to provide an overview of what actually goes in the treatment program. Use available data and existing instruments whenever possible. Work as a team; staff investment in and commitment to the study is a key for a successful project.

Endnote

1. The hypothetical example was created by Mark L. Willenbring, M.D.

Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series

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Chapter 6 -- Cost-Effectiveness of Opioid Substitution Therapy ¹

Alcohol and other drug (AOD) abuse is the Nation's number one health problem, accounting for assignificant portion of the increase in healthcare expenditures. The total economic cost of substance abuse to the U.S. economy each year is staggering, with estimates ranging in excess of \$238 billion ([Institute for Health Policy, 1993](#)). This total includes the direct cost of treatment as well as the opportunity costs or societal costs associated with substance abuse (for example, costs due to lost productivity, illness, and criminal activities).

In 1994, expenditures by Medicaid and Medicare on hospital claims due to AOD abuse and dependence are estimated to reach \$27.4 billion. Substance abuse treatment can greatly reduce healthcare costs. It can also greatly reduce costs associated with crime.

This chapter provides a brief discussion of recent studies showing the effectiveness of AOD abuse treatment. An overview of studies measuring the cost-effectiveness of treatment is presented, and the difficulty of designing and conducting research on costs of treatment is discussed. Four methods that have been used to estimate treatment costs are presented, and estimates of the costs of methadone treatment are given. Cost elements that should be collected routinely in order to do a comprehensive and accurate cost analysis are listed. The chapter also includes a brief discussion of the various ways that benefits have been measured. The methods used by New York and Massachusetts to determine costs of their opioid substitution therapy services are presented, and the advantages and disadvantages of these methods are discussed.

The phased model of treatment presented in [Chapter 3](#) can be helpful in making decisions about resource allocations, and the chapter includes a discussion of the types and levels of resources needed during each phase.

For readers who are interested in cost research, Appendix C presents several methodological approaches to consider in designing research that might enhance the AOD treatment field's knowledge base.

One factor that must be emphasized when evaluating the cost-effectiveness of opioid substitution therapy is that the target population is chronically and persistently ill. Chronic illness usually is associated with increased costs per patient. Outcomes in this population are defined differently; other treatment modalities may define positive outcome as the successful completion of treatment and the ability of the patient to remain clean and sober. When evaluating overall effectiveness, a sophisticated approach must be used that addresses the actual delivery of services per patient rather than a narrowly defined outcome.

One factor that must be emphasized when evaluating the cost-effectiveness of opioid substitution therapy is that this population is chronically and persistently ill. Chronic illness is usually associated with increased costs per patient.

In addition, interprogram cost comparisons are rarely true indicators of quality or effectiveness, mainly because there is so much variability among programs and because appropriate psychiatric and medical services are often unavailable onsite. Comparisons are sometimes used by insurers to force providers into lower levels of service delivery, whereas providers should be encouraged to augment and enhance their services. The cost benefit has to be aligned with the long-term improvement of the chronic patient and his or her needs for a range of services. In this sense, it may be effective to compare costs to treat a patient in opioid substitution therapy with the costs of treating the same patient in a different modality, or to refer patients out to several systems (medical, psychiatric, and AOD treatment systems) simultaneously. It may be appropriate for a cost-per-patient rate in a specific region to be used to prevent providers from being discouraged from delivering comprehensive services.

The Effectiveness of Treatment: Recent Reports

Although controversy exists about the methodologies and measures used in outcomes research, there is general agreement that treatment is effective in reducing drug use, decreasing criminal activity, and improving health outcomes ([Apsler and Harding, 1991](#); [Institute of Medicine, 1990b](#); [Keeler et al., 1986](#); [McLellan et al., 1983](#)).

The CALDATA Study and the NASADAD Report

As this Treatment Improvement Protocol (TIP) was being prepared for publication, results of an important long-term study on the effectiveness of AOD abuse treatment were published ([California Department of Alcohol and Drug Programs, 1994](#)). The 2-year California Drug and Alcohol Treatment Assessment (CALDATA) study followed a rigorous probability sample of the nearly 150,000 persons who received AOD abuse treatment in California in 1992. The sample included patients in a spectrum of treatment modalities, including patients in continuing methadone treatment. The cost of treating the approximately 150,000 participants in 1992 was \$209 million, while the benefits received during treatment and in the first year afterwards were

worth approximately \$1.5 billion.

Thus, for every dollar spent on treatment, more than \$7 in future costs were saved. These savings were largely in relation to reductions in criminal activity and in the number of hospitalizations for health problems. For a smaller sample followed through the second year, results have indicated that projected cumulative lifetime benefits of treatment will be substantially higher than the shorter term benefits.

The CALDATA study found that, from before to after treatment, criminal activity declined by two thirds and hospitalizations by one third. Declines of about two fifths also occurred in the use of alcohol and other drugs from before to after treatment was received. Treatment for problems caused by the use of major stimulant drugs (crack cocaine, powdered cocaine, and methamphetamine), which were all in widespread use, was found to be just as effective as treatment for alcohol problems and somewhat more effective than treatment for heroin problems. No differences in treatment effectiveness were found by gender, age, or ethnic group.

In addition to the recent data from California, a substantial body of evidence has been accumulated on the effectiveness of alcohol and other drug treatment programs ([Anglin and Hser, 1990](#); [Young, 1994](#)). The National Association of State Alcohol and Drug Abuse Directors (NASADAD) has recently compiled a report that summarizes studies performed in 15 States on the effectiveness of AOD treatment ([Young, 1994](#)). Studies examined the effects of treatment on health status, workers' productivity, and criminal behavior. These studies found decreases in hospitalizations ranging from 36 percent in California to 66 percent in Ohio. States averaged an increase of more than 70 percent in the number of persons who were employed after treatment. The proportion of persons who were arrested after treatment dropped dramatically; Iowa showed a 50 percent decrease, and Ohio a 90 percent decrease.

Variation in Costs and Treatment Outcomes

Tremendous variability exists in the types, duration, and costs of treatment. For example, the CALDATA study reported costs per day of treatment in various modalities. The average treatment lasted 95 days (excluding continuing methadone clients). The treatment costs per day were residential, \$61.47; social model, \$34.41; outpatient drug free, \$7.87; methadone continuing, \$6.37; and methadone noncontinuing (primarily opiate detoxification), \$6.79.

Treatment outcomes vary widely among programs, even among programs that deliver the same types of services. However, studies such as the CALDATA study that have examined a wide range of treatment alternatives, including methadone treatment, have shown that opioid substitution therapy programs have outcomes similar to those of other types of treatment programs. The exception is programs offering detoxification alone, which typically show no long-term benefits.

The CALDATA study showed that for every dollar spent on treatment, more than \$7.00 in future costs were saved. These savings were largely in relation to reductions in criminal activity and in the number of

hospitalizations for health problems.

However, because the positive effects of treatment often dissipate quickly after the patient leaves the treatment setting, substance abuse treatment may be cost effective only for those who remain in treatment for a substantial time ([Anglin and Hser, 1990](#)). Because substance abuse is a chronic condition associated with high recidivism or relapse rates, the findings of cost-effectiveness studies of particular programs are difficult for policymakers to evaluate.

Review of Cost-Effectiveness Studies

Recent Studies

In the last several years, demands for greater treatment capacity for persons with alcohol and drug disorders have increased at the same time that State governments and private insurers have implemented cost constraints. This situation has led to a proliferation of studies on the cost-effectiveness of treatment programs.

In 1991, the National Institute on Drug Abuse published its first technical review on substance abuse financing and services research ([National Institute on Drug Abuse, 1991](#)). Included in that publication was a review of the current status of cost-effectiveness analyses ([Apsler and Harding, 1991](#)), which cited the difficulties of analyzing cost-effectiveness data. The review pointed out the absence of consensus regarding a definition of substance abuse and dependence, the lack of clarity concerning the goals of treatment, and the differences in interventions used by various programs that employ the same treatment modality. For example, different outpatient methadone programs use different interventions; interventions also differ among outpatient drug-free settings, therapeutic communities, and detoxification programs.

In a review of studies on cost and cost-effectiveness, [French and associates \(in press\)](#) found that most studies used different cost accounting methods, making the results difficult to compare.

The most frequently mentioned studies on the cost-effectiveness of substance abuse programs are those of [Harwood and colleagues \(1984\)](#), [Hubbard and associates \(1989\)](#), and [McGlothlin and Anglin \(1981b\)](#). The findings from these studies support the premise that substance abuse programs have been both cost beneficial to the client in treatment and cost effective in terms of AOD treatment service delivery. In all of these studies, the monetary value of "benefits" to individuals who receive substance abuse treatment has been based on aggregate data, which are then used to estimate individual costs. For example, the cost of crime for each subject is estimated based on national figures developed from the U.S. Department of Justice and the Bureau of Justice Statistics Reports.

[Harwood and colleagues \(1988\)](#) used data from the Treatment Outcome Prospective Study (TOPS) to examine the monetary consequences of substance abuse with respect to crime. TOPS is a longitudinal survey of 11,000 drug abusers in 10 cities, a survey which used a cost methodology developed by [Harwood and others \(1984\)](#). Using national statistics, the

methodology estimated dollar costs for three kinds of drug-related crime -- victim costs, criminal justice system costs, and crime career or productivity costs. Using a pre-post study design, criminal activity in the year before and the year after treatment was assessed for patients in residential, outpatient methadone, and outpatient drug-free programs. The results showed that the average benefit per day for all treatment modalities exceeded the average cost of treatment per day.

Because substance abuse is a chronic condition associated with high recidivism or relapse rates, the findings of cost-effectiveness studies of particular programs are difficult for policymakers to evaluate.

The benefit of reduction in criminal activity of those who are opioid addicted is directly tied to length of stay in a treatment program. In a study of six methadone maintenance clinics by [Ball and Ross \(1991\)](#), the average length of patient stay was 4.5 years. When patients dropped out of treatment, most relapsed to drug abuse within 1 year, often returning to previous criminal patterns to support the addiction.

[Hubbard and associates \(1989\)](#) analyzed the costs of 41 substance abuse treatment programs for 11,000 individuals who entered selected programs between 1979 and 1981. Clients in three major treatment modalities were assessed: 1) outpatient methadone maintenance, 2) therapeutic community, and 3) outpatient drug-free programs. Study participants were interviewed at admission, 3 months, 1 year, 2 years, and 3 to 5 years after leaving treatment. The authors concluded, based on self-reports of the clients, that treatment resulted in substantial decreases in the abuse of both opioid and nonopioid drugs. However, very few patients achieved the goal of abstinence. Based on participant interviews, Hubbard and colleagues also found a substantial reduction in crime-related costs. Investigators concluded that these reductions were "at least as large as the cost of providing treatment, with much of the expenditure recovered during the time the drug abuser was in treatment."

The benefit of reduction in criminal activity of those who are opioid addicted is directly tied to length of stay in a treatment program. In one study, when patients dropped out of treatment, most relapsed to drug abuse within 1 year, often returning to previous criminal patterns to support the addiction.

In [McGlothlin's and Anglin's study \(1981b\)](#) of the effects of closing a methadone maintenance program, the social costs incurred in a community where a program was closed were compared with the costs in a comparison community where a drug treatment program continued to operate. Rough estimates were obtained for the costs of treatment, arrest and court processing, jail, probation, forgery, robbery, and welfare. The overall results showed that for males, mean annual costs per subject in the community with the closed program were approximately 17 percent

higher than those in the comparison community.

Methods of Estimating Treatment Costs

The majority of cost-effectiveness studies of substance abuse treatment have used one of the following methods, described by [French \(in press\)](#), to estimate the cost of drug treatment programs:

- **Method 1.** Identification and summation of all funding sources as an estimate of program costs ([National Drug and Alcoholism Treatment Unit Survey \[NDATUS\], 1993](#)). Although, in a perfect world, revenues should equal expenditures, many resources in these programs may be donated or shared, resulting in an underestimation of real operating costs.
- **Method 2.** Calculation of expenditures minus avoided costs or benefits. This is a cost-benefit approach that estimates program treatment costs (including the costs to patients, such as transportation, day care, and so forth) and subtracts the monetary benefits associated with treatment, such as reduced welfare payments, increased wages, and reduced incarceration. Estimates of social benefits such as criminal activity are frequently based on self-reports from participant interviews.
- **Method 3.** Calculation of program operating costs with no adjustments for economic costs, such as costs of volunteers, donations, start-up capital costs, opportunity costs, and so forth.
- **Method 4.** Financial accounting models using fixed costs, such as capital and depreciation costs, and variable costs, such as those for personnel, supplies, and operating costs. Average cost per client and incremental or marginal costs can be estimated from these data.

In a recent study comparing the cost-effectiveness of standard versus enhanced methadone programs ([Bradley et al., 1994](#); [French, in press](#)), a costing methodology developed at [Research Triangle Institute \(1993\)](#) and based on standard accounting procedures was implemented. Using the approach described in method 4, cost data were collected using an instrument known as [DATCAP \(Research Triangle Institute, 1993\)](#), a lengthy cost worksheet that is personally administered by researchers at the program site. The cost methodology focuses on "program cost," as opposed to client or reimbursers' cost. Cost information is gathered from budgets, audit reports, expense reports, and other documents, with the costs of shared or donated resources based on market value estimates. Costs are subsequently grouped into categories, such as buildings and equipment, rent and maintenance, labor, contracted services, and other variable costs.

These program cost estimates, based on 1990 dollar figures, resulted in an average annual treatment cost per client for standard methadone treatment of \$12 per day or \$4,002 annually, which is double the amount [Harwood and associates \(1988\)](#) estimated based on 1979 figures. Labor, as expected, was the most costly component, ranging between 43 percent and 59 percent of total costs. The estimates by French ([in press](#)) are similar to figures derived from the [National Drug Services Research Survey \(1990\)](#); a median cost per slot for "all" types of drug programs was estimated to be \$4,600 per year ([Horgan, 1991](#)). Opioid substitution therapy is generally thought to be the least expensive treatment modality, although people generally remain in opioid substitution therapy programs longer than in outpatient drug-free treatment. However, it should be kept in mind that costs differ for different treatment modalities and cost comparisons across

modalities should be viewed with caution.

Toward Standardized Methodologies

One of the major obstacles in drawing valid conclusions about the cost effectiveness or cost benefit of substance abuse treatment programs is the failure of investigators to use standard protocols such as DATCAP for identifying cost elements, collecting data, and constructing program cost estimates. Even when cost elements are standardized, the methods for estimating items such as capital and depreciation costs differ considerably across programs, resulting in great variability in estimates. Additionally, programs within a large organization that share resources or use donated or volunteer services often fail to accurately account for these expenditures. Even after items are standardized, collected, and categorized, controls or adjustments must be made for differences across locales in wages, variable demand, program case mix, and so forth.

Based on 1990 dollar figures, the average annual treatment cost per client for standard methadone treatment was estimated to be \$12 per day or \$4,002 annually, which is double the amount Harwood and associates estimated based on 1979 figures.

The following is a list of cost elements that should be collected routinely in order to do a comprehensive and accurate cost analysis:

1. **Program Revenue:**
 - Revenues should be categorized by source, for example, Medicaid, Medicare, Department of Veterans Affairs, self-pay, Federal block grant, State revenues, commercial insurers.
2. **Program Expenditures:**
 - Full-time equivalent (FTE) staff average salary and fringe benefits, including volunteer hours
 - Consultant and or contracted service costs
 - Building costs (square footage), percentage of building used by program, estimated rent if donated or shared
 - Program supply costs
 - Equipment costs (such as furniture, machinery, and computers)
 - Pharmacy and laboratory costs
 - Other costs.
3. **Program Outputs:**
 - Average client caseload, including some measure of case mix
 - Percentage of staff hours in direct treatment
 - Program capacity
 - Types of problems treated (substance abuse, psychiatric, medical, and so forth).

Effectiveness Measures

Although a major focus of cost-effectiveness studies is monetary issues, attention must also be paid to identifying and defining the effectiveness or benefit measures that result from substance abuse treatment. The least expensive method of treatment is not always the most cost effective. Since clinical outcomes research has been a primary focus of the substance abuse research community for decades, this area is better defined and measured than research in the area of program costs. Instruments for assessment and patient evaluation have been used extensively for many years and are found to be reliable.

As long as the outcome indices are measured in the same way and interrater reliability is ensured, a number of effectiveness indices are appropriate for cost-effectiveness analyses. The indices most often used in prior studies are level of reduction in substance use, increase in employment and number of days worked, reduction in criminal activity and incarceration, and more appropriate use of the healthcare system. Although no single measure can encompass the total impact of a program intervention, multiple indices can be examined and used to identify cost-effective programs. More will be said about the multidimensional nature of the outcomes measures in the next section.

Directions for Future Research

Despite all of the difficulties associated with cost-effectiveness analyses, there is no reason why comparable cost and outcomes information on a program level cannot be collected and used to develop comparable cost-effectiveness ratios. However, since substantial variability is known to exist among substance abuse treatment programs with respect to organizational structure, financial funding streams, manpower mix, cost of care, and efficacy of treatment ([Wheeler et al., 1992](#)), the characteristics of cost-effective programs will have to be examined to determine whether findings can be generalized.

More work must be done on the characteristics of programs and the features or best practices that foster cost-efficient and cost-effective treatment outcomes. Studies that investigate the characteristics of programs that provide clients with adequate care in the least costly manner while controlling for differences in services and populations treated are at the core of the next research frontier area. Another TIP in this series, *Developing State Outcomes Monitoring Systems for Alcohol and Other Drug Abuse Treatment*, examines issues involved in determining what characteristics of programs contribute to better treatment outcomes.

Appendix C presents a discussion of several methodological approaches for readers who are interested in designing and conducting research on costs of treatment.

More work must be done on the characteristics of programs and the features or best practices that foster cost-efficient and cost-effective treatment outcomes.

Allocation of Resources

[Chapter 3](#) of this TIP describes a phased model of treatment in opioid substitution therapy. When treatment is conceptualized as occurring in phases, resources can be identified and allocated according to the type and intensity of services needed during each phase. Knowledge of the distribution of the patient population in the various treatment phases within an opioid substitution therapy program is also helpful in making resource allocation decisions. However, knowledge of the complexity of the patients' associated psychiatric, medical, social, and family problems is crucial to this decisionmaking. For example, one opioid substitution therapy program may treat fewer patients than another program but may need more resources because patients in the program have multiple associated problems, such as human immunodeficiency virus (HIV) disease or severe psychiatric problems. Many of the decisions that are made about program resources depend upon the type and severity of problems presented by the patient population in treatment.

Resource Allocation During the Acute Phase

The acute phase of treatment requires a concentration of resources to achieve stabilization of the range of problems related to drug use, as well as psychiatric, medical, family-social, and other problems. Resources needed in these areas during the acute phase include

1. Comprehensive medical services:
 - Laboratory, including urine testing
 - Increased visits with medical staff (physicians, nurses)
 - Inpatient hospitalization for medical or surgical procedures
 - Increased use of pharmacy services.
 2. Increased psychiatric services:
 - Assessment and diagnosis
 - Pharmacotherapy
 - Psychotherapy
 - Case management.
 3. Increased substance abuse counseling services:
 - Increased individual time with therapist or counselor
 - More frequent walk-in or unscheduled appointments
 - Orientation of patients to the opioid substitution therapy treatment program.
 4. Administrative costs:
 - Increased recordkeeping by program staff
 - Increased attention to patient's adjustment to clinic setting and clinic rules.
 5. Other program resources:
 - Assessment and treatment planning by counselor
 - An increase in the amount of time spent referring patients to other human service agencies
 - Multidisciplinary involvement of program staff, for example, by social workers and psychologists in preparing referrals and following up on patient's contacts.
-

When treatment is conceptualized as occurring in phases, resources can be identified and allocated according to the type and intensity of services needed during each phase.

The mix and level of medical and psychiatric services needed by patients in the acute phase varies as a function of the population served. Some patients are sicker than others and may have a proportionally greater need for ancillary services, such as assessment and treatment for HIV or tuberculosis (TB). These medical and psychiatric services frequently include laboratory work and more frequent visits with physicians and nurses. For the first few days in the acute phase, patients may require as many as two visits daily with medical staff until the acute phase or crisis has passed. In addition, the patient is more likely to need surgical, inpatient hospital, and other acute medical or psychiatric care services and ancillary medication. Increased counseling services in the acute phase include more frequent unscheduled appointments.

More time is spent by counseling staff in getting to know patients, orienting them to the clinic's policies and procedures, reinforcing specific rules, and managing acute problems and referrals. Developing a sense of trust and working with the patient to define treatment goals requires spending increased amounts of time with patients. Increased recordkeeping is also needed in the acute phase because of the significant amount of documentation required in terms of methadone dosage adjustments and stabilization of medical and psychiatric conditions.

During the acute phase, a high level of consultation time is sometimes required with other agencies that provide medical, psychiatric, social, or other services that may not be available onsite to patients in opioid substitution therapy programs. Some examples of offsite services are referrals to primary health clinics that treat patients with HIV or TB, and referrals to housing agencies or mental health services. Psychosocial assessments may require multidisciplinary involvement by members of the treatment team, including social workers and psychologists. Patients with legal or financial problems also may need help managing their problems in these areas. Time spent on treatment planning and coordinating responses to a variety of treatment needs during a patient's admission to the program may be extensive and require input from counseling, social work, legal, and medical staff, who are not always onsite.

Resource Allocation During the Rehabilitation Phase

In the rehabilitation phase, efforts should be directed toward continuing the interventions started during the acute phase at appropriate levels, fine tuning, and offering an array of adjunctive resources such as education and vocational training. During this phase, it may periodically be necessary to return to providing services associated with the acute phase.

More resources must be put into case management in the early part of the rehabilitation phase to ensure that patients' needs are being addressed in each domain. Weekly counseling sessions at the beginning of this phase may gradually decrease to twice a month and eventually to monthly when indicated by the patient's progress and changing needs. A reduced level of resources in the later stages of the rehabilitation phase is appropriate, with some services referred out and others provided onsite as appropriate. However, some patients need ongoing medical, psychiatric, or

other services in all phases of treatment.

More resources must be put into case management in the early part of the rehabilitation phase to ensure that patients' needs are being addressed in each area of their lives.

Resource Allocation During Supportive Care and Medical Maintenance

Patients in these later phases of opioid substitution therapy treatment, by definition, do not need intensive contact with treatment staff, although periodic checks on progress and counseling aimed at sustaining earlier treatment gains are important. Attention to stable but ongoing medical, psychiatric, family-social, and other problems should be continued. Exacerbations of the addiction or of one or more associated problems usually require a return to a more intensive (i. e., acute or rehabilitation) treatment phase. When intensive treatment is resumed, patients often respond quickly and are able to return to a less intensive phase of treatment.

Resource Allocation During the Tapering And Readjustment Phase

Treatment services typically intensify during tapering, but they vary according to individual patients' needs. More frequent counseling and supervision such as once or twice weekly sessions and daily check-ins with a counselor or nurse may be indicated. In general, however, counseling services are not as intensive as in the acute phase. Decisions concerning the frequency and intensity of services must be made according to the treatment providers' clinical judgment.

Ideally, readjustment following completion of detoxification requires an increase or change in the type of resources to help the patient deal with the many issues often involved in remaining successfully drug free over an extended period of time. As stated earlier, patients may choose to enter an inpatient rehabilitation program at the start of this phase, followed by a more prolonged period of outpatient followup therapy.

In practice, the use of associated program resources is sometimes minimal during the readjustment phase. Many patients discontinue clinic visits or contact with any formal treatment program after they complete tapering. If the patient remains in contact with the opioid substitution therapy program, the readjustment phase mainly involves counseling visits, depending on the patient's needs. If a patient is on continuing adjunctive medication such as naltrexone, weekly visits (at a minimum) will most likely be needed. If the patient elects to follow methadone detoxification with a period of intensive rehabilitation, treatment intensity is likely to be increased for the first 2 to 12 weeks, followed by a less intense period of treatment and relapse prevention. In such cases, the rehabilitation treatment is similar to that for persons seeking recovery from addiction to cocaine or alcohol and, in fact, therapy could be provided in a setting where patients with all these problems are being treated, rather than in an opioid substitution therapy program.

Summary

The use of a phased model of opioid substitution therapy allows treatment programs to plan for and cost efficiently allocate resources and to tailor resources to the needs of specific patient populations. With the full implementation of the phased model of treatment, it becomes possible to estimate the proportion of patients within the various phases and allocate resources accordingly. Each patient's needs, however, rather than the phases themselves, should dictate the specific course of treatment. The phases should simply facilitate the natural course of the recovery process.

The use of a phased model of opioid substitution therapy allows treatment programs to plan for and allocate resources and to tailor resources cost-efficiently to the needs of specific patient populations.

The full implementation of this phased model within a treatment system may permit cost sharing of resources during the various phases so that resources are used in the most efficient manner. For instance, a 24-hour medical facility may serve as a resource to patients from several opioid substitution therapy programs that have patients in the acute phase, and a vocational training and education center may serve as a resource for patients from several programs who are in the rehabilitation phase. As this model evolves, each component must undergo critical evaluation from the perspective of patient outcome, cost-effectiveness, and quality improvement so that its advantages and shortcomings can be clearly documented.

Program Cost Issues for Administrators and Program Planners

Staffing Patterns

The largest cost component of opioid substitution therapy programs is personnel. The staffing patterns of methadone maintenance programs may be regulated either by the State or by contract. These standards are usually expressed in the number of full-time-equivalent staff members per number of patients in the program. For example, the number of physicians, registered nurses, pharmacists, LPNs, and substance abuse counselors may be specified. In addition, overhead costs of administrative and support service staff, as well as the cost of laboratory, pharmacy services, and facility maintenance staff are figured into the cost per patient.

Services Other Than Substitution Therapy

Opioid substitution therapy programs have expanded their scope in order to address the crises of ill health and poverty that often accompany opioid addiction. Because of the high incidence of poor health and infectious disease in injecting-drug-using populations, basic healthcare services are now often provided onsite. The provision of onsite healthcare services in opioid substitution therapy clinics has been shown to be a more effective public health intervention than referral for

primary care outside of the clinic ([Umbricht-Schneider et al., 1994](#)).

Federal Block Grant regulations require opioid substitution therapy programs to give priority in providing services to certain populations of injecting drug users (for example, pregnant women) or those at risk of transmitting HIV or TB. Additional staff for HIV counseling, referral, and treatment are sometimes hired by substitution therapy programs. Often, these ancillary staff members are paid through special Federal or State grant funds, which are not figured into the reimbursement rate for opioid substitution therapy. In addition, opioid substitution therapy programs are increasingly providing onsite case management of medical and social services for clients.

Calculating Treatment Costs: Two Examples

New York and Massachusetts provide examples of how costs for opioid substitution therapy programs are calculated. Each State has a commission or State authority in charge of rate setting; in New York, the authority is tied to a statewide healthcare financing mechanism. In Massachusetts, the authority is the Massachusetts Rate Setting Commission (RSC). Included in RSC's authority is the setting of rates for substance abuse treatment services that are not acute inpatient services.

New York has enacted Medicaid managed care and employs a Certificate of Need process that determines rates using a Diagnostic-Related Group (DRG) methodology in which costs are tied to treatment for a particular diagnosis. New York's Medicaid rate for opioid substitution therapy services is aggregated. This aggregation means that the unit cost per patient per week reflects the cost for all services available to the patient in the program, including the various costs for providing the methadone dose and the additional costs for providing counseling and other services.

On the other hand, Massachusetts has an unaggregated rate for opioid substitution therapy. Under this arrangement, there is one set charge for all services that are considered to be medical, or connected to methadone dosing, and a second, separate charge for counseling services.

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Cost Elements

Currently, the State of New York reimburses methadone treatment providers at \$100 per week per Medicaid patient. This rate is based on the following cost elements

- Urine drug testing
- Dispensing of methadone
- Medical supervision of dosing process and ordering laboratory tests
- Annual physical examinations
- Preparation and monitoring of treatment plans
- Maintenance of patients' medical histories
- Prescribing methadone dosage
- Counseling as prescribed in the treatment plan
- Maintenance of records
- Physician services, nursing services, therapist services, and technician services
- Nutrition services
- Health education services
- Psychosocial services
- Care coordination services (case management).

The Massachusetts Rate Setting Commission currently sets the cost per day per patient at \$9.61 (\$67.27 per week). The amount includes costs for all of the medical service units listed below in calculating a cost per day for providing a dose of methadone:

- Medical assessment, including limited physical examination
- Laboratory tests
- HIV risk assessment
- Medication (dosing)
- Medication dispensing
- Drug screening
- Medical case management
- Assessment of client status, treatment planning, and periodic reassessment of treatment plans
- Arranging for primary care, home care, hospitalization, and consultation with other medical care providers
- Interventions for health maintenance and risk reduction, including treatment compliance counseling and nutrition maintenance, HIV risk reduction, and counseling about other chronic illnesses.

As described above, Massachusetts has an unaggregated rate, and the cost per patient for providing outpatient counseling services is calculated separately. The RSC has set the following rates for various types of counseling service units. These services are the same as those provided for all other substance abuse counseling programs:

- Individual counseling, \$51.08 per hour
- Group counseling, \$19.88 per hour
- Couples/family counseling, \$61.32 per hour.

It should be noted that ongoing treatment for psychiatric and medical conditions by appropriately trained personnel is not part of either reimbursement system. Were these services to be charged to the programs with onsite delivery or by close affiliations and networks, the overall costs of the programs would increase. However, patient compliance increases when these services are readily available, and overall healthcare costs may decrease because of reductions in emergency room

visits and unscheduled inpatient care.

Advantages and Disadvantages of the Two Approaches

There are some benefits and drawbacks to the methods used by each State in establishing the reimbursable rate for opioid substitution therapy services. The aggregate rate permits smooth functioning of opioid substitution therapy programs, with no peaks and valleys in funding, while making time services (mainly AOD treatment services) available to all patients based on need. Including costs for all elements of treatment in one rate, however, may make it difficult for programs to know their costs based on a phased treatment model or to cost out the elements of treatment for patients with particular needs.

An unaggregated reimbursement rate offers much more control for the program and the State in cost containment. Since budgeting in Massachusetts is based on capitation, with Federal and State funds folded in, patient mix is the key to program costs. Programs are able to design a service package for each client based on budget and contract allocations. With an unaggregated rate, programs have more flexibility in developing a budget based on a phased approach. Not every patient will need \$4,000 a year, for example, for opioid substitution therapy treatment. The costs will vary by program and will be based on the patient's needs. Some patients will need more counseling than others, and therefore one program may budget for more billing in counseling services than another program. If a program has more patients in the supportive care phase of treatment, then counseling costs will probably be less.

Conclusions

Resources for providing effective opioid substitution therapy are limited. In the national arena, recent debates about healthcare reform have drawn attention to improving the delivery of all types of healthcare services, including substance abuse treatment, and to making these services more accessible and more effective while holding down costs. Increasingly, under managed care, service providers will compete for resources. Programs must pay detailed attention to costs and to refinement of the provision of services so that the most appropriate interventions are provided for each patient. Creating cost-effective programs and matching patients to treatment services share these goals. An important factor in estimating costs is determining the costs to the overall healthcare system that can be saved by delivering readily available psychiatric and medical services. This strategy is consistent with patient-treatment matching and efficient service delivery.

Endnote

1. Parts of this chapter were written for the consensus panel by Aileen B. Rothbard, Sc.D., and Arie P. Schinnar, Ph.D., of the University of Pennsylvania. The chapter focuses on cost issues in methadone programs only, since cost-effectiveness research on levo-alpha-acetyl methadol (LAAM) is still being conducted.

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Matching Treatment to Patient Needs in Opioid Substitution Therapy

Treatment Improvement Protocol (TIP) Series 20

Appendix A -- Bibliography

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Appendix B -- Massachusetts Methadone Treatment Criteria

Introduction

The Massachusetts Methadone Treatment Criteria were developed and written by the Massachusetts Methadone Treatment Providers Association. The American Society of Addiction Medicine (ASAM) has not, as yet, published admission, continuing care, and discharge criteria for methadone treatment. Therefore, although these criteria were modeled on the format and conceptualization of the ASAM criteria, the content is original work.

Several challenges were present in the development of methadone treatment criteria. First, methadone treatment, including admission into this service, is a heavily regulated substance abuse treatment modality on both the state and federal level. For example, methadone treatment is regulated for the type of substance being abused (opiates); the length and severity of addiction (1 year or more); a client's age (18 years or older); and several other issues. Therefore, the development of admission criteria needed to address and incorporate each applicable regulation.

Secondly, writing discharge criteria for methadone treatment is complex and variable on a number of levels. For example, methadone treatment can be either a short-term or a long-term treatment approach. In some instances it is a lifetime treatment modality. This variability, dependent on the goals and objectives of individualized treatment plans, made the development of uniform discharge criteria challenging. The Massachusetts Methadone Treatment Providers have successfully developed criteria that capture and address these complex issues.

A. Brief Description of Treatment Level

An organized, ambulatory addictions service for opiate addicted clients with designated addiction trained personnel and/or addiction credentialed clinicians that provide individualized treatment, case management, and health education including HIV, TB, and STD. The nature of the services (e.g., level of dose, length of stay, frequency of visits) is correlated with the client's clinical needs, but consists of regularly scheduled psychosocial treatment sessions and daily medication visits within a structured program. These services function under a defined set of policies and procedures; admission, discharge, and ongoing treatment criteria are also stipulated by state (DPH 105 CMR 750.720) and Federal regulations (FDA 21 C.F.R. Part 291 Vol.54 No.40 p.8962).

Methadone treatment is designed to address the client's individual needs to achieve changes in the individual's level of functioning, including elimination of illicit opiate and other drug abuse including alcohol. To accomplish this, the program addresses major lifestyle, attitudinal, and behavioral issues which can undermine the goals of treatment and inhibit the individual's ability to cope with major life tasks.

B. Programmatic Description

1. Setting

A professional setting that includes permanent Free-Standing Clinic sites, Community Mental Health Centers, Community Health Centers, Hospitals, Medication Units, Satellite Clinics, or Mobile Units attached to a permanent clinic site.

2. Support Systems

- a. Linkage or access to psychological, medical and psychiatric consultation.
- b. Linkage or access to emergency medical and psychiatric affiliations with more intensive levels of care as needed.
- c. Linkage or access to evaluation and ongoing primary medical care.
- d. Ability to conduct and/or arrange for appropriate laboratory and toxicology tests.
- e. Physician availability to provide evaluation for, prescription of, and on-going monitoring of methadone; nursing and/or pharmacy availability for the dispensing and administering of methadone.
- f. Provisions for the safe storage of methadone.

Note: The preference is that programs have direct access to or on-site services; however, linkage to these services may suffice if direct access is not available.

3. Staff

- a. A multidisciplinary team of appropriately trained and/or credentialed addictions professionals, including a medical director, physicians, nurses, and counselors. May include licensed psychologists and registered pharmacists as needed. They must be knowledgeable in the assessment, interpretation, and treatment of the biopsychosocial dimensions of drug and alcohol dependence. Staff members shall receive supervision appropriate to their level of training and experience.
- b. Licensed medical staff (nursing, medical, or pharmaceutical) is available to administer medications in accordance with the physician's prescription and/or orders. The intensity of

nursing care is appropriate to the services provided by an outpatient methadone treatment program.

c. A physician is available during medication dispensing and clinic operating hours either in person or by telephone.

4. Therapies

a. Multidisciplinary individualized assessment and treatment are provided.

b. Medication: Assessment, prescribing and administering adequate doses of methadone are provided; overseeing and facilitating access to appropriate treatment including medication for other physical and mental health disorders are provided as needed.

c. Counseling: A range of cognitive, behavioral, and other addictions-focused therapies reflecting a variety of treatment approaches are provided to the client on an individual, group, and family basis.

d. Case Management: Case management including medical monitoring and/or coordination of off site treatment services are provided as needed.

e. Psychoeducation including AIDS and other health education services are provided.

f. Provisions for or referral to vocational counseling, treatment of psychiatric illness, primary health care, and other adjunctive services are provided as needed.

5. Assessment/Treatment Plan

a. A comprehensive medical history, physical examination and laboratory tests must be provided or obtained. For clients seeking admission, tests must include the following: [blood analysis (CBC and differential, liver function); routine and microscopic urinalysis; Tuberculin test; Australian antigen HB Ag; Hepatitis Core Antibody (HBc Ab); pregnancy test; Syphilis Serology; Urine toxicology; and EKG, when appropriate,] are obtained upon admission (and annually thereafter or more often if indicated). These tests must be done on admission and reviewed by the physician [within 14 days of prescribing and administering of methadone. (Federal Register, Department of Health and Human Services, Food and Drug Administration 21 CFR Part 291 Vol.54, No.40, March 1989, p.8962-8964, and in Massachusetts, Department of Public Health, 105 CMR 750.720, p.21-23).]

b. An appropriate methadone dose is established by the physician upon admission, and reviewed annually, or more frequently as indicated during the client's course of treatment.

c. In the presence of life-threatening biomedical problems, continuing evaluation and referral by the program physician as required. These conditions include but are not limited to:

1. Recurrent or multiple seizures; or

2. Excessive use of alcohol, cocaine, or other drugs that can result in stupor, seizures, etc.; or
3. Mental status indicators that require inpatient management (e.g., depression with suicide ideation, attempts, psychosis, etc.); or
4. Biomedical problems that require 24-hour observation and evaluation.

d. The nurse (physician or pharmacist) is responsible for overseeing the monitoring of client progress and medication administration at each medication visit.

e. Individual biopsychosocial assessments are made of all clients.

f. Treatment plan reviews are conducted at specific times as noted in the treatment plan (e.g., 90 days intervals).

6. Documentation

a. Progress notes in the client's record are recorded at each face-to-face contact and clearly reflect implementation of the treatment plan as well as the client's response to treatment.

b. Documentation is recorded for each dose of methadone administered.

C. Diagnostic Admission Criteria

The client is assessed as meeting the diagnostic criteria for psychoactive substance use disorder as defined by current *Diagnostic and Statistical Manual of Mental Disorders* (DSM) or other standardized and widely accepted criteria.

In instances whereby the presenting drug-alcohol history is inadequate to substantiate such a diagnosis, the material submitted by other medical and health care professionals and/or programs, collaterals (e.g., family members, legal guardians, significant others) indicates a high level of probability of such a diagnosis based upon further evaluation.

Clients admitted into methadone treatment must demonstrate specific objective and subjective signs of opiate dependence as defined in the *Federal Register*, Department of Health and Human Services Food and Drug Administration, 21 C.F.R. Part 291, Vol.54, No.40, 1989.

D. Dimensional Admission Criteria

Admission into this level of care requires meeting the specifications for dimensions 1, a., b., and c., or one of the exception admission criteria defined in d., e., and f., and at least one of each of the dimensions of 2-6.

1. Acute intoxication and/or Withdrawal:

a. The physician determines that the client is "physiologically dependent upon an opiate drug and became physiologically dependent at least 1 year before admission for methadone maintenance."

This means the client was addicted "continuously or episodically for most of the year immediately before admission." (FDA 21 C.F.R. Part 291 Vol.54 No.40 p.8962-3); and

b. Criteria to determine the client's current physiological dependence and history of addiction include but are not limited to vital signs, early physical signs of narcotic withdrawal, a positive urine screen for opiates, presence of old or fresh needle marks, documented medical and/or treatment history, client and/or family report, etc. (DPH 105 CMR 750.720); and

c. Exceptions for penal or chronic care may be admitted into methadone treatment within 14 days of release or within 6 months after release without documented evidence of physiological dependence provided that the individual was eligible for admission prior to incarceration. (FDA 21 C.F.R. Part 291 Vol.54 No.40 p.8963); or

d. Pregnant clients who have a documented opiate dependency history may be placed on methadone treatment without documentation of physiological dependence if the program physician certifies the pregnancy and finds treatment to be "medically justified (FDA 21 C.F.R. Part 291 Vol.54 No.40 p.8963); or

e. Previously treated clients: Under certain circumstances a client who has had previous methadone treatment and later voluntarily detoxified from methadone, may be readmitted to methadone treatment without evidence of current physiological dependence, up to two years after discharge, if the program is able to document prior methadone treatment of six months or more and in the program physician's reasonable judgment readmission to methadone treatment is medically indicated. (Federal Register, Department of Health and Human Services, 21 C.F.R. Part, 291,505(c) p.130.)

2. Biomedical Conditions and Complications

Must meet a and may meet b-c.

a. Biomedical criteria for opiate dependence with or without the complications of opiate addiction requiring medical monitoring and skilled care; or

b. Concurrent biomedical illnesses or pregnancy that can be stabilized and maintained safely on an outpatient basis with minimal daily medical monitoring; or

c. Presence of non-acute biomedical problems that can be managed on an outpatient basis and do not require inpatient treatment, such as:

1. Liver disease, or problems with potential hepatic decompensation;
2. Pancreatitis;
3. Gastrointestinal problems;
4. Cardiovascular disorders;
5. HIV, AIDS, and other sexually related conditions;
6. Sexually transmitted diseases;
7. Concurrent psychiatric illness requiring sychotropic medications;

8. Concurrent psychiatric illness requiring psychotropic medications;
9. Tuberculosis.

3. Emotional/Behavioral Conditions and Complications

Must meet one of the criteria defined in a-f.

- a. Emotional/behavioral complications of addiction are present and are manageable in an outpatient structured environment; or
- b. Addiction related abuse/neglect of spouse/children/significant others requiring intensive outpatient treatment to reduce the risk of further deterioration; or
- c. Emotional/behavioral complications related to HIV infection, AIDS, and sexually transmitted diseases; or
- d. Diagnosed and stable emotional/behavioral or thought disorder which requires monitoring, management, and/or psychotropic medication due to a history indicating its high potential of distracting the client from recovery and/or treatment (e.g., stable borderline personality, compulsive personality, etc.); or
- e. Mild risk of behaviors endangering self or others with or without a history of severe depression, suicidal and/or homicidal behavior that can be managed safely in a structured outpatient environment.
- f. Emotional/behavioral stability are present but continued pharmacotherapy is required to prevent relapse to illicit opiate use.

4. Treatment Acceptance/Resistance

Must meet one of the criteria defined in a or b.

- a. The client requires structured therapy, methadone and programmatic milieu to promote treatment progress and recovery.
- b. The client attributes problems to persons or external events and not to client's addiction. This inhibits client's ability to make behavioral changes without clinically directed and repeated structured motivating interventions. The client's resistance is not so high as to render the treatment ineffective.

5. Relapse Potential

Must meet one of the criteria defined in a-c.

- a. The client requires structured therapy, methadone and programmatic milieu to promote treatment progress and recovery because the client attributes continued relapse to physiological cravings/need for opiates; or
- b. Despite active participation at a less intensive level of care (e.g., outpatient counseling), and/or other treatment interventions without the provisions for methadone, the client is experiencing an intensification of addiction symptoms (e.g., difficulty postponing immediate gratification and related drug-seeking behavior), or continued high risk behaviors (e.g., shared needle use), and the individual has a deteriorating level of functioning despite revisions in the treatment plan; or
- c. The client is at high risk for relapse to opiate use without methadone, close outpatient monitoring and structured support as indicated, for example, by lack of awareness of relapse triggers, difficulty postponing immediate gratification, and/or ambivalence/resistance to treatment.

6. Recovery Environment

Must meet one of the criteria defined in a-c.

- a. A sufficiently supportive psychosocial environment makes outpatient methadone treatment feasible, (e.g., significant others are supportive of recovery efforts, supportive work or legal coercion, adequate transportation to program is available, support, etc.); or
- b. Family/significant others are supportive, but require professional interventions to improve chances of treatment success and recovery of the client (e.g., assistance in limit setting, communications skills, decrease rescuing behaviors, education about methadone treatment, AIDS education, etc.); or
- c. Even though the client does not have an ideal primary or social support system to assist with immediate recovery efforts, or may be homeless, the client has demonstrated motivation and willingness to obtain such a support system and/or pursue with assistance adequate shelter to create an environment conducive for outpatient methadone treatment; or
- d. Emotional/behavioral complications of addiction are present that are manageable in an outpatient structured environment. These behaviors include:
 - 1. Illicit/criminal activity;
 - 2. Victim of abuse or domestic violence;
 - 3. Unable to maintain a stable household, including providing for food, consistent shelter, supervision of children, and health care;
 - 4. Unable to attain or keep a job.

E. Length of Stay

Length of stay will vary with the severity of the client's illness.

F. Continued Stay Criteria

Continued stay requires meeting specifications in I and II.

I. Diagnosis

The client is assessed as meeting the diagnostic criteria for psychoactive substance abuse disorder as defined by the current *Diagnostic and Statistical Manual of Mental Disorders* (DSM) (Opiate Dependence Continuous -- 304.00) or other standardized and widely accepted criteria.

II. Dimensional Continuing Stay Criteria

Continued stay requires meeting the specification for dimensions 1., a-c and at least one specification of each of the dimensions of 2-6.

1. Acute drug dependence and/or Potential Relapse:

Must meet one of the criteria defined in a-c.

- a. Continued methadone maintenance is required to prevent potential relapse to opiate use;
- b. Client continues to need ongoing medical monitoring and access to medical management;
- c. Client continues to have the presence of adequate support services to ensure commitment to and entry into continued addictions treatment.

2. Biomedical Conditions and Complications

Must meet one of the criteria defined in a-c.

- a. Continued presence of biomedical condition and opiate dependence problem requires medical monitoring and/or medical management and skilled care; or
- b. Presence of or threat of increased rate of one or more of the following:
 - 1. Episodic use of drugs other than narcotics;
 - 2. Positive HIV status or AIDS
 - 3. Chronic health conditions that could be medically compromised with discontinuation of methadone maintenance treatment including but not limited to:
 - Liver disease, or problems with the potential hepatic decompensation;
 - Pancreatitis;
 - Gastrointestinal, cardiovascular, and other systems disorders;
 - HIV, AIDS, and other sexually related conditions;
 - Sexually transmitted diseases;
 - Concurrent psychiatric illness requiring psychotropic medications;
 - Tuberculosis; or

c. Client is a pregnant opiate dependent woman.

3. Emotional/Behavioral Conditions And Complications

Must meet one of the criteria defined in a-g.

a. The client has achieved stable emotional/behavioral functioning that may be jeopardized by discontinuation of methadone treatment.

b. The client demonstrates the potential for making use of methadone treatment but may not have made significant life changes. (Client participates in the program, attends counseling, has decreased illicit activity, etc.); or

c. The client is making progress towards resolution of an emotional/behavioral problem, but has not sufficiently resolved problems to allow transfer from methadone maintenance to a less intensive level of care; or

d. The client's emotional/behavioral disorder, which is being concurrently managed, continues to distract the client from focusing on treatment goals, but the client is responding to treatment, and it is anticipated that with further interventions, will be able to achieve treatment objectives; or

e. The client continues to manifest mild risk behaviors endangering self or others (e.g., periodic shared needle practices, unprotected sexual activities, some outside drug use), but the condition is improving; or

f. The client is being "held" pending transfer to a more intensive treatment service (inpatient or residential care); or

g. The client continues high risk behaviors for HIV exposure with or without the presence of HIV disease; or

h. Diagnosed and stable emotional/behavioral or thought disorder which requires monitoring, management, and/or psychotropic medication due to a history indicating its high potential of distracting the client from recovery and/or treatment (e.g., stable borderline personality, compulsive personality, etc.).

4. Treatment Acceptance/Resistance

Must meet one of the criteria defined in a-c.

a. The client recognizes the severity of the drug problem, but demonstrates minimal understanding of self-defeating use of drugs (or alcohol), yet the client is progressing in treatment; or

- b. The client recognizes the severity of the drug problem and manifests understanding of his/her relationship with psychoactive substances, yet does not demonstrate behaviors that indicate client has assumed responsibility necessary to cope with the problem; or
- c. The client is beginning to recognize responsibility for addressing the drug problem, but still requires this level of intensity of motivating strategies to sustain personal responsibility in treatment.
- d. The client has accepted responsibility for drug problem and has determined that ongoing methadone treatment is the most effective means of preventing relapse to drug addiction.

5. Relapse Potential

Must meet one of the criteria defined in a-c.

- a. The client requires structured therapy, methadone and the programmatic milieu to promote continued progress and recovery because attributes continued relapse to physiological cravings/need for opiates; or
- b. The client recognizes relapse triggers, but has not developed sufficient coping skills to interrupt or postpone gratification, or to change inadequate impulse-control behaviors; or
- c. Addiction symptoms, while stabilized, have not sufficiently been reduced to support functioning outside of a structured milieu.
- d. Methadone has served as part of an effective treatment to alleviate addiction symptoms and prevent relapse, and the withdrawal of methadone is likely to lead to a recurrence of addiction symptoms.

6. Recovery Environment

Must meet one of the criteria defined in a-f.

- a. The client has not integrated sufficient coping skills to withstand stressors in the work environment or has not developed vocational alternatives; or
- b. The client has not yet developed sufficient coping skills to deal with the non-supportive family/social environment or has not developed alternative living support systems; or
- c. The client has not yet integrated the socialization skills necessary to establish a supportive social network; or
- d. Problem aspects of the client's social and interpersonal life are responding to treatment, but are not sufficiently supportive of recovery to allow transfer to a less intensive level of care; or

e. The social and interpersonal life of the client has not changed or has deteriorated, and the client needs additional treatment to learn to cope with the current situation or take steps to secure an alternative environment; or

f. Emotional/behavioral complications of addiction are still present, are manageable in an outpatient structured environment, but need more work. These behaviors include:

1. Illicit criminal activity;
2. Victim of abuse or domestic violence;
3. Unable to maintain a stable household, including providing for food, consistent shelter, supervision of children, and health care;
4. Unable to attain or keep a job.

g. The social and interpersonal life of the client has stabilized while in methadone treatment and is supportive of continuing methadone treatment.

G. Discharge Criteria

The client is considered eligible for discharge from this level of care when the conditions in I and II below are fulfilled.

I. Diagnosis

1. The client is assessed as meeting the diagnostic criteria from opiate dependence in remission without the need for methadone; or
2. The client is diagnosed with continuing opiate dependence requiring another level of care.

II. Dimensional

Discharge requires meeting the specifications for dimension 1 and at least one of each of the specifications for dimensions 2-6.

1. The client does not meet any of the dimensional continuing stay criteria.
2. Biomedical Conditions and Complications:

Must meet one of the criteria defined in a or b.

a. The client's biomedical condition and opiate dependence problem has stabilized and can be managed without continued use of methadone, and the client does not meet any of the continued stay criteria that indicate the need for further methadone treatment; or

b. Continued methadone treatment presents a serious medical risk as determined by the program's medical director. Continued treatment is required in another treatment setting.

1. Emotional/Behavioral Conditions and Complications

Must meet one of the criteria defined in a or b.

- a. The client's emotional or behavioral problems have diminished or stabilized to the extent that they can be managed through outpatient counseling and/or self-help fellowship, and the client does not meet any of the continued stay criteria that indicate the need for further methadone treatment; or
- b. A psychiatric/emotional/behavioral condition exists that is interfering with addiction treatment in an outpatient methadone treatment setting.
 - 1. Continued participation in a methadone treatment program presents a serious psychiatric risk as determined by the program's medical director.
 - 2. Continued treatment is required at a more intensive level of care.

2. Treatment Acceptance/Resistance

Must meet all of the criteria defined in a, 1-3 or b.

- a. The client's awareness and acceptance of an addiction problem and commitment to recovery is sufficient to expect maintenance of recovery through outpatient counseling and/or a self-directed recovery plan as evidenced by:
 - 1. The client is able to recognize the severity of their drug problem; and,
 - 2. The client demonstrates an understanding of a self-defeating relationship with psychoactive substances; and,
 - 3. The client is applying the essential skills necessary to maintain a stable recovery program without methadone at this time in either methadone aftercare treatment, outpatient drug-free counseling services and/or self-help fellowship; or
- b. The client has consistently failed to achieve essential treatment objectives despite revisions to the treatment plan to the degree that the client needs placement at a more intensive level of care.

3. Relapse Potential

Just meet one of the criteria defined in a or b.

- a. The client recognizes relapse triggers and has developed sufficient coping skills to interrupt or postpone gratification and impulse control behaviors without methadone. The client may need the continued support of outpatient counseling to maintain recovery.
- b. The client is experiencing a continuation or exacerbation in drug-seeking behaviors or craving that is not responding to outpatient methadone treatment and has been determined to require more intensive level of care.

4. Recovery Environment

Must meet one of the criteria defined in a, b, or c.

- a. The client's social system and significant others are supportive of recovery to the extent that the client can adhere to a self-directed recovery plan without substantial risk of relapse, and the client does not meet any of the continued stay criteria for methadone treatment; or
- b. The client is functioning adequately and does not meet any of the continued stay criteria that indicate the need for further methadone treatment; or
- c. The client's social system remains non-supportive or has deteriorated. The client is having difficulty coping with this environment and is at substantial risk of relapse. The client is unable to achieve essential treatment objectives within their current social environment.

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Appendix C -- Methodological Approaches to Cost-Efficiency and Cost-Effectiveness Analyses ¹

This appendix provides a conceptual framework for conducting cost-effectiveness analysis. It uses some innovative methodologies that have not been used to date in the substance abuse treatment field. The methodological approaches focus on five specific concerns or issues:

- What is the most cost-effective way to implement a program? An intervention?
- Among several programs performing in a most cost-effective way, which is the most efficient and effective program intervention?
- What is the best way to index efficiency and effectiveness when measures involve multiple outcomes and multiple cost components?
- How does one integrate a variety of different cost-effective measures into a program that maximizes patient benefits and minimizes cost over the entire period of treatment?
- What is the most productive scope of program intervention on a societal level? How large should the program be in relation to its overall societal benefit?

In the following sections, these methodological areas are briefly discussed and some examples of the applications of these methods are provided.

Method 1: Intraprogram Cost-Effective Implementation

The first step in any cost-effectiveness analysis involves ascertaining which is the optimal or most efficient and effective implementation of the program. Without ascertaining the most cost effective implementation, it is impossible to make a comparison between multiple programs. For example, comparing a well-designed program that is poorly implemented with another program that is perhaps less cost effective but well managed may produce results contrary to expectations.

To develop this notion, utilization review concepts used by healthcare management personnel are employed, as well as average cost function methods used by economists. The intent is to ascertain at what point a program, as it is administered over time, achieves the maximum benefit to the patient, per unit cost.

In microeconomics, this maximum benefit is analogous to the average cost curve where program efficiency is viewed as a point where production is at such a level that marginal cost equals average cost.

The approach discussed here differs from the traditional economic one in that the product or the output (that is, the effectiveness of the program) is allowed to vary over time; that is, changes in the functional status of the treated population in a particular program may vary as the program is being administered.

The utilization review methodology ascertains the point in patient treatment when the marginal gain in program or individual goal is no longer justified by the cost of the program. The combination of the two concepts of utilization review and average cost function allows for the determination of the optimal implementation for each program. For example, if counseling visits beyond ten, on average, for patients in methadone treatment programs are found to bring no additional benefits (that is, additional gains in level of functioning), can we justify continuation of counseling treatment?

One approach to developing this methodology further is to use an algorithm that can be adapted to a variety of program modalities. A standardized package of instruments for measuring outcomes and cost, as well as procedures for calculating the optimal implementation point would be disseminated and tested. The methodology could be refined by introducing client characteristics into the algorithm equations in order to control for case mix differences across programs. Given the fact that resources are scarce and demand continues to increase, it is essential to target resources efficiently and effectively. One way to do this is to use a rationale for providing a certain number of treatment sessions based on some optimum level of cost and outcome.

Method 2: Cost-Effective Selection Among Programs

Once the most cost-effective implementation of each program is established, it is possible to ascertain which program intervention is most efficient or effective according to established criteria. This methodology is the most common application of the cost-effectiveness literature wherein a variety of programs are examined and the most cost-effective one is selected. As discussed above, unless each program is implemented in a most cost-efficient way, such comparisons are likely to be meaningless.

For example, consider the comparison of a minimal versus moderate level of counseling support for two types of methadone programs. In the first program, methadone treatment is accompanied by weekly counseling sessions, and in the second, there is additional medical care, career counseling, and family support groups. The comparison between the two programs in terms of which is the most cost effective should first be based on the optimal implementation of each program. At that point the application of standard cost-benefit analysis involving either benefit-to-cost ratios or the difference between benefits and cost can be used to choose the most cost-effective program.

This implementation of the cost-effectiveness methodology will, however, require allowance for different client groups and population attributes. For example, the minimal methadone program implementation may be most suitable for a population which is gainfully employed, whereas the more intensive or moderate program will be more appropriate for a population that is unemployed. Cost effectiveness should always be considered with reference to its

appropriateness for particular population groups. In the first case, one should always seek to implement the most cost-effective protocol of the program. Otherwise, its potential cannot truly be realized. In the second case, the issue is which program gives the most per dollar spent and at the same time is the most appropriate for a particular population group.

Method 3: Efficiency Versus Effectiveness in Program Implementation

The measurement of efficiency, in standard economic applications, uses production economics to determine optimal output. In these types of applications there is an assumed direct mapping between the resources utilized and the output and outcomes of the resources. In the social and health science field, the production function which maps the intervention and the outcome is much more complicated.

Our approach to measuring and indexing efficiency differs from conventional economic methods in that it differentiates between efficiency and effectiveness. In the first case, efficiency is measured by ascertaining the degree to which a program or the implementation of a program for a particular client achieves its maximum efficiency. We do this by comparing resource utilization per output with reference to programs providing similar activities.

In the second case, we establish a reference frontier which reflects the best practice in the conversion of activities to outcomes. Here we measure effectiveness. The distinction made between efficiency and effectiveness enables us to ascertain a relationship between the two.

A number of previous studies (Schinnar et al., 1990, 1993, 1993a)² have demonstrated that the relationship between efficiency and effectiveness is curvilinear in that minimum effectiveness is observed at both minimum and maximum levels of efficiency, and maximum effectiveness is found at a moderate or middle range of efficiency. This measurement suggests that some moderate level of efficiency and effectiveness may be the one that is most optimal for program implementation.

Another important aspect of the measurement of efficiency and effectiveness is the indexing procedure. As demonstrated in a variety of studies in the area of substance abuse, the measurement of outcomes requires multiple indicators. Similarly, the measurement of cost also involves multiple dimensions such as the direct cost of program provision; the cost to the client for services such as childcare, transportation; lost employment opportunity, and so forth; and the societal benefit that occurs from reductions in crime and costly medical utilization.

Similarly, program activities involve many interventions such as counseling, medical care, and vocational assistance. How does one combine these multiple measures into a single index? Today, most methodologies involve the development of multiple ratios of inputs to outputs or outcomes to costs, followed by applying ad hoc procedures to obtain aggregations of these indexes. We suggest the use of a novel methodology known as Best Practice Frontier Analysis to develop measures of efficiency and effectiveness to effect such aggregations (Schinnar, 1980; Charnes et al., 1978)³. The method has been tested and used for the past 15 years in numerous applications and enables the derivation of distinct indexes for efficiency and effectiveness involving measures and scales spanning multiple dimensions. The method also circumvents the

problem of the need to convert such scales into commensurate dimensions as is often done in cost calculations used in traditional cost-benefit analysis. In this manner, cost can be measured in dollars or in time lost or in a variety of other ways (i.e., family burden) without the need to convert these into monetary values which, at times, trivialize the true meaning of the measure itself.

In addition to the measurement of efficiency and effectiveness, multivariate regression methodology can be used to test hypotheses regarding causes for efficiency and effectiveness, as well as to ascertain what organizational determinants, client case mix factors, or funding mechanisms, and so forth are discretionary in affecting the performance of the program. The index of program efficiency and effectiveness is used as the dependent variable and regressed on a list of client, provider and organizational/program characteristics.

Method 4: Interprogram Cost Effectiveness

Drug abuse is viewed as a chronic disease that requires long-term treatment, occasionally continuously and at other times intermittently. If one considers an episode of illness and the treatment during that episode, one must analyze the progression of the patient through various stages of the illness or disease. Our objective in exploring these issues is to develop the appropriate methodology to explain or model this process and to determine the optimal or most cost-effective assignment of programs to clients at various stages of their illness.

Recognizing that there is considerable uncertainty associated with the effectiveness of the program and the transition between one stage of illness and another, we propose the application of dynamic programming techniques ([Bellman and Dreyfus, 1962](#))⁴ to develop the most cost-effective assignment or choice of program for various stages of the client's treatment progression. The methodology partitions the illness and the stages of treatment into various milestones determined by a panel of experts. The next step is to identify the probabilities of transition between the various stages and list the optimal programs available for treatment in these stages. An objective function maximizes, over time, the benefit-to-cost ratio of the administration of the program and selects for each stage the most optimal program to be administered in order to produce the most cost-effective sequence of programs throughout the entire course of the treatment. Such dynamic programming protocols could also be developed for different types of patients based on various attributes.

The key to this methodology is that, unlike traditional cost-benefit analysis, which looks at each stage for particular client populations and chooses the optimum strategy, this strategy allows us to look at the entire treatment process rather than each individual episode. The utility of this particular approach would be at a systems or policy level rather than the individual program level where the question pertains to specific program design implementation. In this case, the question pertains to developing a complete system of programs that coordinates the sequencing of patients between these programs in a way that would maximize their benefit from the treatment.

Method 5: Cost-Effective Sizing of Program Intervention

In this methodological exploration, we move from the clinical outcome domain of cost-effectiveness to address a broader societal question. The question to be addressed is what is the most cost-effective level of treatment for the population as a whole as compared to the benefits from the treatment to society.

For example, should we treat only the most severely ill patient, should we treat those who are employed, should we treat those who are unemployed, and should we treat those who are moderate drug abusers with the chance that they may deteriorate? Clearly, with each of these populations and severity of drug abuse, there is an associated program cost as well as a social opportunity cost. Our objective is to extrapolate from the microanalysis level of specific programs the point of intervention where the marginal gains to society from further drug treatment are offset by the increasing cost of program administration.

A methodology needs to be developed that addresses the concept and provides some guidance in answering this question. The intent would be to find ways to link, methodologically, the clinical level cost-effectiveness studies to more general policy questions regarding the intensity of intervention in this field and its overall cost to our economy.

Summary

A methodological overview has been presented of techniques and approaches that may be useful in ascertaining the cost effectiveness and cost benefit of substance abuse treatment programs. In addition, the type of data that are required to do effective cost analyses is described. Important policy questions have been raised related to identifying the most effective sequence of programs over time for chronic abusers, as well as the optimal allocation of resources that should be devoted to drug abuse. Given the competition that exists in the health and welfare domain for limited resources, those in the substance abuse field will need to develop tools to identify which programs provide optimal treatment in the most cost-efficient manner and what level of programming is appropriate from a cost-beneficial societal view.

Endnotes

1. Material in this appendix was written by Aileen B. Rothbard, Sc.D., and Arie P. Schinnar, Ph.D., of the University of Pennsylvania.
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Exhibits

Exhibit 2-1 DSM-IV Diagnostic Criteria for Substance Dependence

The DSM-IV defines alcohol and other drug addiction as "substance dependence" and describes the diagnostic criteria as a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by three or more of the following occurring at any time in the same 12-month period:

1. Tolerance, as defined by either of the following
 - The need for markedly increased amounts of the substance to achieve intoxication or desired effect
 - Markedly diminished effect with continued use of the same amount of the substance
2. Withdrawal, as manifested by either of the following
 - The characteristic withdrawal syndrome for the substance
 - Use of the same (or closely related) substance to relieve or avoid withdrawal symptoms
3. The substance often taken in larger amounts or over a longer period than was intended
4. A persistent desire or unsuccessful efforts to cut down or control substance use
5. A great deal of time spent in activities necessary to obtain or use the substance or to recover from its effects
6. Important social, occupational, or recreational activities given up or reduced because of substance use
7. Continued substance use despite knowledge of having had a persistent or recurrent physical or psychological problem that was likely to have been caused or exacerbated by the substance.

Adapted with permission from the Diagnostic and Statistical Manual, Fourth Edition (American Psychiatric Association, 1994).

Exhibit 2-2 ICD-10 Criteria for Substance Use Dependence

1. A strong desire or sense of compulsion to take the substance
2. Difficulties in controlling substance-taking behavior in terms of its onset, termination, or level of use
3. A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by the characteristic withdrawal syndrome for the substance or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms
4. Evidence of tolerance that requires increased doses of the psychoactive substances in order to

achieve effects originally produced by lower doses

5. Progressive neglect of alternative pleasures or interests because of psychoactive substance use, or increased amounts of time necessary to obtain, take, or recover from the substance's effects
6. Persistence in the use of the substance despite clear evidence of harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning.

Adapted with permission from the International Classification of Diseases (World Health Organization, 1992).

Phases of Treatment Model for Methadone Treatment

Exhibit 3-1

Phases of Treatment Model for Methadone Treatment

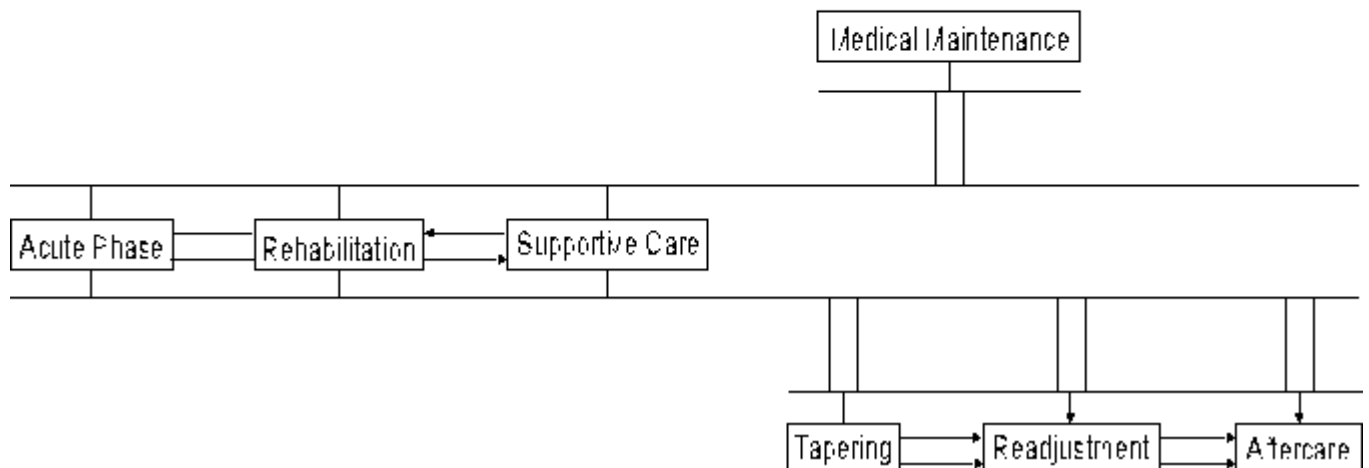


Exhibit 3-2 Acute Phase of Methadone Treatment: Clinical Issues, Strategies, and Issues for Transition to Rehabilitation Phase

Clinical Issues	Strategies to Address Issues	Indicators for Transition Into Rehabilitation Phase
Drug Use and Withdrawal <ul style="list-style-type: none">Adequacy of methadone dose in suppressing withdrawal symptomsContinued use of opioids	<ul style="list-style-type: none">Evaluate and communicate the need for dosage adjustments to adequate dosage (120-160 mg)Accessible clinic hoursIntensify treatment	<ul style="list-style-type: none">Elimination of opioid withdrawal signs, including drug cravingSense of well-beingAbility to avoid

<ul style="list-style-type: none"> • Use of alcohol and other illicit drugs 	<p>strategies; if no reduction in AOD use, refer to inpatient treatment</p> <ul style="list-style-type: none"> • Encourage attendance at self-help groups such as Alcoholics Anonymous and Narcotics Anonymous 	<p>situations that perpetuate continuing drug use</p> <ul style="list-style-type: none"> • Acknowledgement of addiction as problem and motivation to effect lifestyle changes
<p>Medical and Psychiatric Problems</p> <ul style="list-style-type: none"> • Medical <ul style="list-style-type: none"> ◦ cavitary disease, pneumonia; hepatitis A,B,C,D; cellulitis ◦ Sick cell ◦ Hemophilia • Surgical <ul style="list-style-type: none"> ◦ Lung abscesses, skin replacement, renal failure • Psychiatric illness <ul style="list-style-type: none"> ◦ Psychotic, anxiety, mood, and personality disorders • High-risk behaviors 	<ul style="list-style-type: none"> • Linkages to available resources, including medical/psychiatric and emergency services, between physician and hospital • Ongoing counseling to reduce risk 	<ul style="list-style-type: none"> • Stabilization of acute medical crises • Ongoing established care for chronic conditions
<p>Basic Needs</p> <ul style="list-style-type: none"> • Concerns over legal and financial issues • Threats to personal safety • Housing • Transportation • Lack of financial resources • Childcare • Pregnancy • Advocacy 	<ul style="list-style-type: none"> • Referrals to appropriate agencies • Establish linkages and quick referral sources to obtain needed services • Transportation arranged with other patients • Maintain travel resources, including bus tokens and travel vouchers • Identify legal advocate, eligibility case manager, or social worker to identify financial resources 	<ul style="list-style-type: none"> • Provisions made for food, clothing, housing, and safety needs and financial assistance if necessary • Relatively stable and secure living conditions • Receives prenatal care • Childcare resources established • Transportation resources available
<p>Therapeutic Relationship</p> <ul style="list-style-type: none"> • Establishing trust and feeling 	<ul style="list-style-type: none"> • Ensure that methadone dosage is adequate (60-120 mg) 	<ul style="list-style-type: none"> • Regular attendance at group, individual, or (if indicated)

<p>of support</p> <ul style="list-style-type: none"> • Myths surrounding methadone treatment (e.g., "Methadone gets into your bones.") 	<ul style="list-style-type: none"> • Foster atmosphere of trust, familiarity (e.g., introduce patients to key staff members, encourage acquaintance with other patients) • Remain consistent yet flexible and readily available during acute situations • Nonjudgmental attitude • Address relationships (drug, lifestyle, etc.) that have negative influence on patient • Provide incentives, stress benefits of treatment: <ul style="list-style-type: none"> ○ Financial concerns ○ Self-esteem and sense of well-being ○ Freedom from drug cravings • Minimize waiting times during scheduled appointments to demonstrate that the patient's time is valued • Help create support system (e.g., encourage patient involvement in self-help, social, and recreational activities) • Dispel myths surrounding methadone treatment (include family as indicated) 	<p>family counseling</p> <ul style="list-style-type: none"> • Positive interaction with treatment providers • Focus on appropriate range of treatment goals
<p>Motivation/Patient Readiness</p> <ul style="list-style-type: none"> • Ambivalent attitudes about stopping illicit drugs • Involuntary discharge • Negative relationships with staff • Introduction of methadone treatment without needed adjunctive support services 	<ul style="list-style-type: none"> • Ensure that methadone dosage is adequate (60-120 mg) • Address ambivalence about giving up drugs, fears of making major life changes (Miller and Rollnick, 1991) • Stress benefits of methadone treatment: 	<ul style="list-style-type: none"> • Commitment to the treatment process • Acknowledgement of addiction as a problem • Beginning of changes in lifestyle and of addressing issues surrounding drug

<ul style="list-style-type: none"> • Inadequate dosing • Perception that methadone is a medication, not a means of social control • Developing positive attitude for treatment 	<ul style="list-style-type: none"> • Preventing needle-borne infections <ul style="list-style-type: none"> ◦ Avoiding arrest and incarceration ◦ Peace of mind, relief of concerns over obtaining next fix • Encourage patient to control his/her addiction 	abuse
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Exhibit 3-3 Rehabilitation Phase of Methadone Treatment: Clinical Issues, Strategies, and Issues for Transition to Supportive Care

Clinical Issues	Strategies to Address Issues	Indicators for Transition Into Supportive Care
Alcohol and Drug Use <ul style="list-style-type: none"> • Continued use of abusable drugs (alcohol, cocaine, and others) • Continued opioid use 	<ul style="list-style-type: none"> • Behavioral contracting • Short-term inpatient treatment • Disulfiram for alcohol abuse • Intensification of treatment services • Positive incentives: take-home medication, recognition of progress • Intensified individual or group counseling • Adjustments in dosage as necessary for continued opioid use • Support groups 	<ul style="list-style-type: none"> • Ability to identify and manage relapse triggers • Repertoire of coping skills • Demonstrated changes in life circumstances to prevent relapse • Discontinuation of opioid and other drug use • Absence of problematic alcohol use
Medical and Psychiatric Problems and Concerns <ul style="list-style-type: none"> • Chronic medical diseases: diabetes, 	<ul style="list-style-type: none"> • Onsite primary care or linkage to other services • Holistic approach • Training on diet, 	<ul style="list-style-type: none"> • Compliance with treatment for chronic diseases • Improved overall health status

<p>hypertension, HIV infection, tuberculosis, seizure disorders</p> <ul style="list-style-type: none"> • Psychotic, anxiety, mood, and personality disorders • Pregnancy, dental problems, nicotine dependence 	<p>exercise, smoking cessation</p> <ul style="list-style-type: none"> • Adjustments in other medications interacting with methadone • Teach coping skills • Individualized psychiatric care • Early identification and referral for special psychiatric problems • Referral for psychotropic medication or psychotherapy as indicated • Ongoing evaluation of psychiatric status 	<ul style="list-style-type: none"> • Improved dental health and hygiene • Regular prenatal care • Stable medical and mental health status
<p>Vocational and Educational Needs</p> <ul style="list-style-type: none"> • Unemployment/underemployment • Low reading skills • Literacy • Learning disabilities 	<ul style="list-style-type: none"> • Targeting of patients with less than high school education • Onsite GED counseling or referral • Literacy and vocational programs • Encourage local businesses to set up apprenticeships or entry-level positions • Bring together business, government, and industry leaders to set up income-generating enterprise • Training on 	<ul style="list-style-type: none"> • Stable source of income • Actively seeking employment • Involvement in productive activity: school, employment, volunteer work

	budgeting of personal finances	
Family Issues <ul style="list-style-type: none"> • Absence of family support system • Emergence of family problems (e.g., traumatic family history, problematic current situations) 	<ul style="list-style-type: none"> • Involvement in community or church groups • Join fellowship, recreation, or other peer group • Increased involvement in family life (in absence of family dysfunction that impedes progress) • Encourage well-baby care 	<ul style="list-style-type: none"> • Social support system in place • Absence of major conflict within support system • Increased responsibility for dependents
Legal Issues <ul style="list-style-type: none"> • Criminal charges • Custody battles • Ongoing illegal activities 	<ul style="list-style-type: none"> • Access to legal counsel • Encourage patient to take responsibility for legal problems • Identify obstacles to eliminating illegal activities and replacing them with constructive activities 	<ul style="list-style-type: none"> • Resolution of, or ongoing efforts to resolve, legal problems • Absence of illegal activities

Exhibits

Exhibit 2-1 DSM-IV Diagnostic Criteria for Substance Dependence

The DSM-IV defines alcohol and other drug addiction as "substance dependence" and describes the diagnostic criteria as a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by three or more of the following occurring at any time in the same 12-month period:

1. Tolerance, as defined by either of the following
 - The need for markedly increased amounts of the substance to achieve intoxication or desired effect

- Markedly diminished effect with continued use of the same amount of the substance
- 2. Withdrawal, as manifested by either of the following
 - The characteristic withdrawal syndrome for the substance
 - Use of the same (or closely related) substance to relieve or avoid withdrawal symptoms
- 3. The substance often taken in larger amounts or over a longer period than was intended
- 4. A persistent desire or unsuccessful efforts to cut down or control substance use
- 5. A great deal of time spent in activities necessary to obtain or use the substance or to recover from its effects
- 6. Important social, occupational, or recreational activities given up or reduced because of substance use
- 7. Continued substance use despite knowledge of having had a persistent or recurrent physical or psychological problem that was likely to have been caused or exacerbated by the substance.

Adapted with permission from the Diagnostic and Statistical Manual, Fourth Edition (American Psychiatric Association, 1994).

Exhibit 2-2 ICD-10 Criteria for Substance Use Dependence

1. A strong desire or sense of compulsion to take the substance
2. Difficulties in controlling substance-taking behavior in terms of its onset, termination, or level of use
3. A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by the characteristic withdrawal syndrome for the substance or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms
4. Evidence of tolerance that requires increased doses of the psychoactive substances in order to achieve effects originally produced by lower doses
5. Progressive neglect of alternative pleasures or interests because of psychoactive substance use, or increased amounts of time necessary to obtain, take, or recover from the substance's effects
6. Persistence in the use of the substance despite clear evidence of harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning.

Adapted with permission from the International Classification of Diseases (World Health Organization, 1992).

Phases of Treatment Model for Methadone Treatment

Exhibit 3-1

Phases of Treatment Model for Methadone Treatment

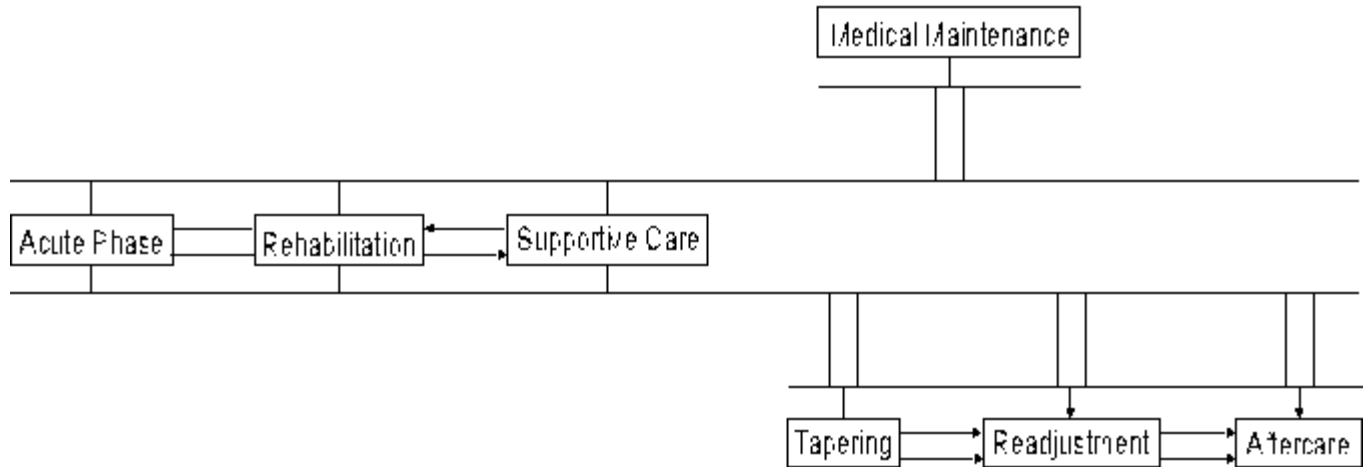


Exhibit 3-2 Acute Phase of Methadone Treatment: Clinical Issues, Strategies, and Issues for Transition to Rehabilitation Phase

Clinical Issues	Strategies to Address Issues	Indicators for Transition Into Rehabilitation Phase
Drug Use and Withdrawal <ul style="list-style-type: none">Adequacy of methadone dose in suppressing withdrawal symptomsContinued use of opioidsUse of alcohol and other illicit drugs	<ul style="list-style-type: none">Evaluate and communicate the need for dosage adjustments to adequate dosage (120-160 mg)Accessible clinic hoursIntensify treatment strategies; if no reduction in AOD use, refer to inpatient treatmentEncourage attendance at self-help groups such as Alcoholics Anonymous and Narcotics Anonymous	<ul style="list-style-type: none">Elimination of opioid withdrawal signs, including drug cravingSense of well-beingAbility to avoid situations that perpetuate continuing drug useAcknowledgement of addiction as problem and motivation to effect lifestyle changes
Medical and Psychiatric Problems	<ul style="list-style-type: none">Linkages to available resources, including	<ul style="list-style-type: none">Stabilization of acute medical crises

<ul style="list-style-type: none"> • Medical <ul style="list-style-type: none"> ◦ cavitary disease, pneumonia; hepatitis A,B,C,D; cellulitis ◦ Sickle cell ◦ Hemophilia • Surgical <ul style="list-style-type: none"> ◦ Lung abscesses, skin replacement, renal failure • Psychiatric illness <ul style="list-style-type: none"> ◦ Psychotic, anxiety, mood, and personality disorders • High-risk behaviors 	<p>medical/psychiatric and emergency services, between physician and hospital</p> <ul style="list-style-type: none"> • Ongoing counseling to reduce risk 	<ul style="list-style-type: none"> • Ongoing established care for chronic conditions
<p>Basic Needs</p> <ul style="list-style-type: none"> • Concerns over legal and financial issues • Threats to personal safety • Housing • Transportation • Lack of financial resources • Childcare • Pregnancy • Advocacy 	<ul style="list-style-type: none"> • Referrals to appropriate agencies • Establish linkages and quick referral sources to obtain needed services • Transportation arranged with other patients • Maintain travel resources, including bus tokens and travel vouchers • Identify legal advocate, eligibility case manager, or social worker to identify financial resources 	<ul style="list-style-type: none"> • Provisions made for food, clothing, housing, and safety needs and financial assistance if necessary • Relatively stable and secure living conditions • Receives prenatal care • Childcare resources established • Transportation resources available
<p>Therapeutic Relationship</p> <ul style="list-style-type: none"> • Establishing trust and feeling of support • Myths surrounding methadone treatment (e.g., "Methadone gets into your bones.") 	<ul style="list-style-type: none"> • Ensure that methadone dosage is adequate (60-120 mg) • Foster atmosphere of trust, familiarity (e.g., introduce patients to key staff members, encourage acquaintance with other patients) • Remain consistent yet flexible and readily available during acute situations • Nonjudgmental attitude 	<ul style="list-style-type: none"> • Regular attendance at group, individual, or (if indicated) family counseling • Positive interaction with treatment providers • Focus on appropriate range of treatment goals

	<ul style="list-style-type: none"> • Address relationships (drug, lifestyle, etc.) that have negative influence on patient • Provide incentives, stress benefits of treatment: <ul style="list-style-type: none"> ○ Financial concerns ○ Self-esteem and sense of well-being ○ Freedom from drug cravings • Minimize waiting times during scheduled appointments to demonstrate that the patient's time is valued • Help create support system (e.g., encourage patient involvement in self-help, social, and recreational activities) • Dispel myths surrounding methadone treatment (include family as indicated) 	
Motivation/Patient Readiness <ul style="list-style-type: none"> • Ambivalent attitudes about stopping illicit drugs • Involuntary discharge • Negative relationships with staff • Introduction of methadone treatment without needed adjunctive support services • Inadequate dosing • Perception that methadone is a medication, not a means of social control • Developing positive attitude for treatment 	<ul style="list-style-type: none"> • Ensure that methadone dosage is adequate (60-120 mg) • Address ambivalence about giving up drugs, fears of making major life changes (Miller and Rollnick, 1991) • Stress benefits of methadone treatment: • Preventing needle-borne infections <ul style="list-style-type: none"> ○ Avoiding arrest and incarceration ○ Peace of mind, relief of concerns over obtaining next fix • Encourage patient to control his/her addiction 	<ul style="list-style-type: none"> • Commitment to the treatment process • Acknowledgement of addiction as a problem • Beginning of changes in lifestyle and of addressing issues surrounding drug abuse

Exhibit 3-3 Rehabilitation Phase of Methadone Treatment: Clinical Issues, Strategies, and Issues for Transition to Supportive Care

Clinical Issues	Strategies to Address Issues	Indicators for Transition Into Supportive Care
<p>Alcohol and Drug Use</p> <ul style="list-style-type: none"> Continued use of abusable drugs (alcohol, cocaine, and others) Continued opioid use 	<ul style="list-style-type: none"> Behavioral contracting Short-term inpatient treatment Disulfiram for alcohol abuse Intensification of treatment services Positive incentives: take-home medication, recognition of progress Intensified individual or group counseling Adjustments in dosage as necessary for continued opioid use Support groups 	<ul style="list-style-type: none"> Ability to identify and manage relapse triggers Repertoire of coping skills Demonstrated changes in life circumstances to prevent relapse Discontinuation of opioid and other drug use Absence of problematic alcohol use
<p>Medical and Psychiatric Problems and Concerns</p> <ul style="list-style-type: none"> Chronic medical diseases: diabetes, hypertension, HIV infection, tuberculosis, seizure disorders Psychotic, anxiety, mood, and personality disorders Pregnancy, dental problems, nicotine dependence 	<ul style="list-style-type: none"> Onsite primary care or linkage to other services Holistic approach Training on diet, exercise, smoking cessation Adjustments in other medications interacting with methadone Teach coping skills Individualized psychiatric care Early identification and referral for special 	<ul style="list-style-type: none"> Compliance with treatment for chronic diseases Improved overall health status Improved dental health and hygiene Regular prenatal care Stable medical and mental health status

	<p>psychiatric problems</p> <ul style="list-style-type: none"> • Referral for psychotropic medication or psychotherapy as indicated • Ongoing evaluation of psychiatric status 	
<p>Vocational and Educational Needs</p> <ul style="list-style-type: none"> • Unemployment/underemployment • Low reading skills • Literacy • Learning disabilities 	<ul style="list-style-type: none"> • Targeting of patients with less than high school education • Onsite GED counseling or referral • Literacy and vocational programs • Encourage local businesses to set up apprenticeships or entry-level positions • Bring together business, government, and industry leaders to set up income-generating enterprise • Training on budgeting of personal finances 	<ul style="list-style-type: none"> • Stable source of income • Actively seeking employment • Involvement in productive activity: school, employment, volunteer work
<p>Family Issues</p> <ul style="list-style-type: none"> • Absence of family support system • Emergence of family problems (e.g., traumatic family history, problematic current situations) 	<ul style="list-style-type: none"> • Involvement in community or church groups • Join fellowship, recreation, or other peer group • Increased involvement in family life (in 	<ul style="list-style-type: none"> • Social support system in place • Absence of major conflict within support system • Increased responsibility for dependents

	absence of family dysfunction that impedes progress) <ul style="list-style-type: none"> • Encourage well-baby care 	
Legal Issues <ul style="list-style-type: none"> • Criminal charges • Custody battles • Ongoing illegal activities 	<ul style="list-style-type: none"> • Access to legal counsel • Encourage patient to take responsibility for legal problems • Identify obstacles to eliminating illegal activities and replacing them with constructive activities 	<ul style="list-style-type: none"> • Resolution of, or ongoing efforts to resolve, legal problems • Absence of illegal activities

Exhibit 3-4 Progress Notes

Patient ID #: _____ Date: ____/____/____ Patient Name: _____ Case Manager: _____ Methadone Dosage: _____ Results of last Urine Toxicology Screen: ____ Positive ____ Negative
1. Medical Sphere: _____ Satisfactory _____ Unsatisfactory Comments: _____ _____ _____

2. Employment Sphere

(including education and training): _____ Satisfactory _____ Unsatisfactory

Comments:

3. Alcohol Use Sphere: _____ Satisfactory _____ Unsatisfactory

Comments:

4. Drug Use Sphere: _____ Satisfactory _____ Unsatisfactory

Comments:

5. Legal Sphere: _____ Satisfactory _____ Unsatisfactory

Comments:

6. Family Sphere: _____ Satisfactory _____ Unsatisfactory

Comments:

<hr/> <hr/> <hr/> <hr/>
<p>7. Psychiatric or Psychological Sphere: _____ Satisfactory _____ Unsatisfactory</p> <p>Comments:</p> <hr/> <hr/> <hr/> <hr/>
<p>Recommendations:</p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <p>Signature: _____</p> <p>(Case manager)</p>

Exhibit 5-1 Evaluation Project: Part 1

Steps of Evaluation	Application of Steps
1. What do you want to know?	<p>A 300-slot community methadone program that collects and tests urine samples, but has little previous evaluation experience, wants to find out</p> <ol style="list-style-type: none"> How common is moderate to severe psychopathology in our population? How effective are we in treating patients with high levels of psychopathology? How often are patients with high levels of psychopathology referred for

	<p>mental health services?</p> <p>4. How often do patients referred for these services receive them?</p>
2. What data are needed?	<ol style="list-style-type: none"> 1. A measure of psychopathology 2. A measure of patient outcome 3. List of services patients are receiving
3. What will be studied?	<ol style="list-style-type: none"> 1. Psychopathology and outcomes will be measured in all patients. 2. Services received will be examined in a 10 percent random sample of patients with a high level of psychopathology. <p>NOTE: This measurement may change depending on the number of such patients found. The idea is to sample enough patients to obtain meaningful data, without being overwhelmed by the task.</p>
4. How will the data be collected?	<p>Instruments:</p> <ol style="list-style-type: none"> 1. To measure psychopathology, use the psychological status section of the <i>Addiction Severity Index</i>. NOTE: There is a need to set a cut-off score for severity. The ASI is a summary measure of the need for treatment in a given area. The recommended cut-off score is 5 on a scale of 1 to 9, but other cut-offs may be chosen, depending on the degree of sensitivity desired. 2. To measure outcome, determine the number of weeks with at least one urine toxicology screen positive for illicit drugs during the past 6 months. (This information has already been tracked by the program and is available.) NOTE: Some programs may not obtain weekly urine samples. A project like this could be modified to accommodate longer intervals between urine screens. 3. To measure process (services received), chart review determining whether a referral was made for mental health services and whether such services were delivered.
5. What are the results?	<ol style="list-style-type: none"> 1. Determine percentage of patients with ASI psychiatric scores greater than 5 (for example, 120 of 300 patients, or 40 percent). 2. Calculate mean number of patients with positive urine screens for groups with low and high levels of psychopathology. (Low: 4.2; High: 12.6) 3. Determine the significance of any difference observed (may need statistical consultant). 4. Determine the proportion of patients with a high level of psychopathology who were referred for mental health services (15 percent), and the percentage who received services (5 percent). <p>NOTE: Determine significance by using any standard statistics program for personal computers. While not essential, determining statistical significance can add weight to the findings. If needed, consider obtaining technical assistance from your State agency,</p>

	a local university, or a graduate student.
6. Do the results answer the questions?	<p>Yes. The results are the following:</p> <ol style="list-style-type: none"> 1. High levels of psychopathology are common (40 percent). 2. The program is much less effective in reducing illicit drug use in the group with high levels of psychopathology than in the group with low levels of psychopathology. Patients with high levels of psychopathology have three times as many positive urine screens as those with low levels. 3. This difference may be due to the fact that very few (15 percent) of the patients with a high level of psychopathology are being referred for mental health services or are receiving them (5 percent).
7. What is next?	<ol style="list-style-type: none"> 1. Examine ways to improve identification of patients with a high level of psychopathology; for example, begin routine use of ASI or the ASI psychological status section. 2. Examine barriers to referring patients to mental health services and to their receiving services. These barriers may include lack of funding, lack of mental health services, and obstructions to admission to mental health programs. Initiate staff discussion about problems and barriers; conduct patient focus groups. 3. Develop strategies for reducing barriers. 4. Repeat study after initiating program changes.

Exhibit 5-2 Evaluation Project: Part 2

Steps of Evaluation	Application of Steps
1. What do you want to know?	<ol style="list-style-type: none"> 1. Did patients with a high level of psychopathology receive services? 2. What problems arose when attempting to implement the intervention? 3. What strategies were used to overcome the barriers? 4. Did obtaining mental health services reduce illicit drug use? <p>NOTE: Questions 1 to 3 are a process evaluation, examining service delivery. This examination includes an implementation analysis (questions 2 and 3). Question 4 is the second outcome analysis.</p>
2. What data is needed?	<ol style="list-style-type: none"> 1. Implementation analysis: Meeting notes, personal log of program director, interviews with case managers and patients. 2. Services received: Chart review of 20 of 120 patients with a high level of psychopathology selected at random. 3. Outcomes: Urine drug toxicology screens (number of weeks of positive urines during last 6 months).

3. Who will be studied?	Sample of patients with a high level of psychopathology.
4. How do you collect data?	<p>Data is collected from existing program sources for all of these processes:</p> <ol style="list-style-type: none"> 1. Implementation: Analysis of narrative, logs, and meeting and interview notes 2. Services received: Chart review on data collection forms from first study 3. Outcome: Urinalysis data (already tracked and available).
5. What are the results?	<p>Implementation analysis:</p> <ol style="list-style-type: none"> 1. Required meeting with program staff to discuss importance of referral and to solve problems related to referral. 2. Some barriers are encountered with staff resistance at mental health agency. These are lessened after an inservice training program conducted by the methadone program staff. 3. Another problem arose with funding. This problem was resolved by the methadone program's agreeing to collect information needed to apply for financial assistance and arranging for rapid processing by the county benefits agency. 4. Patients needed to be educated and reassured about mental health services and persistently encouraged and supported to attend them. 5. Services: Eighteen of 20 patients with high psychopathology received mental health services; 2 of 20 did not, because of persistent refusal to accept referral. 6. Outcome: Average number of positive drug tests went from baseline of 12.6 to 8.2. This was significantly lower than baseline, although still higher than the group with low psychopathology.
6. What do the results mean?	<ol style="list-style-type: none"> 1. It is feasible to screen for and successfully refer patients for mental health services who have a high level of psychopathology. 2. Receiving mental health services resulted in a significant reduction in positive urine drug screens.
7. What is next?	<ol style="list-style-type: none"> 1. Continue screening and referral procedures. 2. Periodically monitor referrals and problems with referrals.